



A REPORT  
TO THE  
MONTANA  
LEGISLATURE

INFORMATION SYSTEMS AUDIT

# *The Montana Prescription Drug Registry*

*Department of Labor and Industry  
Board of Pharmacy*

JUNE 2019

LEGISLATIVE AUDIT  
DIVISION

18DP-01

**LEGISLATIVE AUDIT  
COMMITTEE**

**REPRESENTATIVES**

KIM ABBOTT

[Kim.Abbott@mtleg.gov](mailto:Kim.Abbott@mtleg.gov)

DAN BARTEL

[Danbartel2@gmail.com](mailto:Danbartel2@gmail.com)

TOM BURNETT, VICE CHAIR

[Burnett.tom@gmail.com](mailto:Burnett.tom@gmail.com)

DENISE HAYMAN

[Denise.Hayman@mtleg.gov](mailto:Denise.Hayman@mtleg.gov)

EMMA KERR-CARPENTER

[KC@mtleg.gov](mailto:KC@mtleg.gov)

MATT REGIER

[Matt.Regier@mtleg.gov](mailto:Matt.Regier@mtleg.gov)

**SENATORS**

DEE BROWN

[senatordee@yahoo.com](mailto:senatordee@yahoo.com)

JASON ELLSWORTH

[Jason.Ellsworth@mtleg.gov](mailto:Jason.Ellsworth@mtleg.gov)

JOHN ESP

[Johnesp2001@yahoo.com](mailto:Johnesp2001@yahoo.com)

PAT FLOWERS

[Pat.Flowers@mtleg.gov](mailto:Pat.Flowers@mtleg.gov)

TOM JACOBSON

[Tom.Jacobson@mtleg.gov](mailto:Tom.Jacobson@mtleg.gov)

MARY McNALLY, CHAIR

[McNally4MTLeg@gmail.com](mailto:McNally4MTLeg@gmail.com)

MEMBERS SERVE UNTIL A  
MEMBER'S LEGISLATIVE TERM  
OF OFFICE ENDS OR UNTIL A  
SUCCESSOR IS APPOINTED,  
WHICHEVER OCCURS FIRST.

§5-13-202(2), MCA

FRAUD HOTLINE  
(STATEWIDE)

1-800-222-4446

(IN HELENA)

444-4446

[LADHotline@mt.gov](mailto:LADHotline@mt.gov)

[www.montanafraud.gov](http://www.montanafraud.gov)

**INFORMATION SYSTEMS AUDITS**

Information Systems (IS) audits conducted by the Legislative Audit Division are designed to assess controls in an IS environment. IS controls provide assurance over the accuracy, reliability, and integrity of the information processed. From the audit work, a determination is made as to whether controls exist and are operating as designed. We conducted this IS audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objectives. Members of the IS audit staff hold degrees in disciplines appropriate to the audit process.

IS audits are performed as stand-alone audits of IS controls or in conjunction with financial-compliance and/or performance audits conducted by the office. These audits are done under the oversight of the Legislative Audit Committee, which is a bicameral and bipartisan standing committee of the Montana Legislature. The committee consists of six members of the Senate and six members of the House of Representatives.

---

**AUDIT STAFF**

---

MIKI CESTNIK

AMANDA SAYLER

---

Reports can be found in electronic format at:  
<https://leg.mt.gov/lad/audit-reports>

# LEGISLATIVE AUDIT DIVISION

Angus Maciver, Legislative Auditor  
Deborah F. Butler, Legal Counsel



Deputy Legislative Auditors:  
Cindy Jorgenson  
Joe Murray

June 2019

The Legislative Audit Committee  
of the Montana State Legislature:

This is our information systems audit of Montana Prescription Drug Registry managed by the Board of Pharmacy which is administratively attached to the Department of Labor and Industry.

This report provides the legislature information about improving management and increasing security over the registry. It discusses establishing procedures, increasing system functionality, and clarifying responsibilities. It also includes recommendations for improving data reliability and addressing misuse and diversion of prescription drugs in Montana. Finally, it discusses analyzing resources and actively using the advisory group moving forward. A written response from the department is included at the end of the report.

We wish to express our appreciation to the board and department personnel for their cooperation and assistance during the audit.

Respectfully submitted,

*/s/ Angus Maciver*

Angus Maciver  
Legislative Auditor



## TABLE OF CONTENTS

Figures and Tables.....	iii
Appointed and Administrative Officials .....	iv
Report Summary .....	S-1
<b>CHAPTER I – INTRODUCTION AND BACKGROUND .....</b>	<b>1</b>
Introduction .....	1
Background.....	1
MPDR Funding and Costs .....	2
MPDR Data.....	3
MPDR Submission Process and Use .....	4
The Future of MPDR .....	6
Audit Scope.....	6
Scope Limitation .....	6
Audit Objectives.....	7
Audit Methodologies.....	7
Report Contents.....	8
<b>CHAPTER II –THE BOARD OF PHARMACY NEEDS TO IMPROVE MONTANA PRESCRIPTION DRUG REGISTRY PROJECT AND CONTRACT MANAGEMENT OVERSIGHT .....</b>	<b>9</b>
Introduction.....	9
Multiple Standards Exist to Ensure Funds Are Spent Effectively.....	9
Contract Management and MPDR Development Weaknesses Occurred Throughout System Implementation and Maintenance .....	10
Work Order Does Not Contain Required Language .....	10
Grant Funded Payments Were Made Prior to Deliverables Being Met .....	11
Delayed System Implementation and Missing Documentation Identified.....	12
Minimal Communication and Accountability Contributed to Problems .....	13
MPDR Requires Established Procedures and Responsibilities .....	14
Data Destruction Was Not Timely .....	15
<b>CHAPTER III – SECURITY GOVERNANCE AND USER MANAGEMENT.....</b>	<b>17</b>
Introduction.....	17
MPDR Security Requirements.....	17
Current Security Assurances Are Limited .....	18
Security Governance and Responsibility Is Undefined .....	18
HIPAA Security Rule Is Not Fully Implemented Due to Incomplete Security Management.....	19
User Management Is Crucial for Securing Personal Health Information.....	20
MPDR User Access Structure .....	20
User Management Procedures Need Improvement.....	20
Self-Governing Access Does Not Meet Best Practices .....	22
Current Access Controls Allow Unauthorized Access .....	22
Board Has Not Prioritized User Management .....	24
<b>CHAPTER IV –MONTANA PRESCRIPTION DRUG REGISTRY DATA RELIABILITY .....</b>	<b>25</b>
Introduction.....	25
Reliable and Accurate Data Is Important for Several Reasons .....	25
Some Controls Exist for Correcting Errors .....	26

Data Control Enforcement Should Be Conducted Regularly by the Board.....	27
Board Can Improve MPDR Data Integrity .....	27
Further Data Validations and Review Are Needed to Increase MPDR Usability .....	31
Inconsistent and Out-of-Date Reporting Requirements .....	32
Missing Data Fields Diminish the Usability and Effectiveness of MPDR .....	32
Board Needs to Update Reporting Requirements.....	33

## **CHAPTER V – ACTIVITIES TO IDENTIFY MISUSE AND DIVERSION OF PRESCRIPTION DRUGS.....35**

Introduction.....	35
Criteria to Identify Misuse and Diversion of Prescription Drugs .....	35
Issues With Unique IDs Were Identified .....	36
Potential Evidence of Patient Misuse and Diversion .....	37
Potential Prescriber Misuse and Diversion Can Also Be Identified Using MPDR Data.....	40
Suspicious Activity Needs to Be Defined and Reviewed to Improve Patient Safety.....	42

## **CHAPTER VI – MONTANA PRESCRIPTION DRUG REGISTRY DIRECTION AND RESOURCES.....45**

Introduction.....	45
Coordination of Resources Is Needed to Support Management of MPDR.....	45
Limited Resources Impacted MPDR Planning and Management.....	47
Advisory Group Established to Help Direct MPDR Operations .....	48
More Direction on the Management of MPDR Is Needed From Advisory Group .....	49
Senate Joint Resolution 20 Recommended Registry Enhancements.....	50
Prescription Drug Registry Advisory Group Could Provide Ongoing Guidance on the Registry.....	51
Prescription Drug Registry Advisory Group Requires More Frequent Meetings, Inclusive Membership, and Transparency .....	52

## **DEPARTMENT RESPONSE**

Department of Labor and Industry.....	A-1
---------------------------------------	-----

## FIGURES AND TABLES

### Figures

Figure 1	MPDR Data Flow.....	5
Figure 2	Delegate User Employment Verification: Questionable Delegate Access by Associated User License Type.....	23
Figure 3	Potential Issues Related to Prescription Dates and Refills .....	30
Figure 4	Suspicious Patient Activity Analysis .....	39
Figure 5	Suspicious Prescriber Activity Analysis.....	42

### Tables

Table 1	MPDR Funding and Costs.....	3
Table 2	Prescription Drug Schedule Ratings .....	4
Table 3	System Request Analysis Results.....	13

## APPOINTED AND ADMINISTRATIVE OFFICIALS

### Department of Labor and Industry

Galen Hollenbaugh, Department of Labor and Industry, Commissioner

Todd Younkin, Business Services Division, Administrator

George Parisot, Department of Labor and Industry, Chief Information Officer

Judy Bovington, Department of Labor and Industry, Chief Legal

Marcie Bough, Board of Pharmacy, Executive Officer

			<u>Term Expires</u>
<b>Board of Pharmacy</b>	Starla Blank, President, Pharmacist	Clancy	2019
	Marian Jensen, Secretary, Public Member	Butte	2022
	Courtney Bahny, Certified Pharmacy Technician	Helena	2023
	Mike Bertagnolli, Pharmacist	Three Forks	2020
	Paul Brand, Pharmacist	Florence	2019
	Tony King, Pharmacist	Helena	2021
	Charmell Owens, Public Member	Missoula	2023





# MONTANA LEGISLATIVE AUDIT DIVISION

## INFORMATION SYSTEMS AUDIT

### The Montana Prescription Drug Registry

Board of Pharmacy

Department of Labor and Industry

JUNE 2019

18DP-01

REPORT SUMMARY

The Montana Prescription Drug Registry (MPDR) tracks prescribed and dispensed medications within Montana or to its residents. This allows Montana prescribers and pharmacists to search patient medical history for controlled substances. MPDR is administered by the Board of Pharmacy and is a tool for prescribers to improve patient care and safety. The registry can also be used to identify potential misuse or diversion of prescription medications. Roughly \$1.8 million has been spent on the registry since 2012. However, significant improvement is needed related to registry oversight and maintenance, data reliability, and effective analysis of prescription data to identify potential misuses or diversion of prescribed medications. The Board of Pharmacy needs to play a more active role in these efforts to achieve the intent of the registry.

### Context

The Board of Pharmacy (board) is responsible for ensuring pharmacies and pharmacists are practicing within law and rule. The board is also responsible for the governance of the Montana Prescription Drug Registry (MPDR) and ensuring pharmacies properly report prescription drug data to the registry. MPDR was authorized by the Montana Legislature in 2011 (§37-7-15, MCA) and it became functional in November 2012. The registry serves as an online tool providing a list of dispensed controlled substance prescriptions to prescribers and pharmacists to improve patient care and safety. This includes using information to identify potentially inappropriate dispensing and prescribing of prescription medications, which is known as misuse and diversion.

MPDR contains personal health information (PHI), which is protected by the Health Insurance Portability and Accountability Act (HIPAA). Information includes patient names, prescriber information, pharmacy information, and prescription history. Medical professionals

and pharmacists register to access this information and can search patient history to review past prescriptions for suspicious activity or to verify current prescriptions.

The registry is primarily funded through prescriber and pharmacist license fees. Previously, the board received federal grant money to further expand the registry and its capabilities. However, the board did not receive grant dollars after 2017 and has since been relying on license fees to maintain the registry.

The board has dedicated one full-time position responsible for managing the registry's day-to-day functions. According to the position description, it handles system development and testing, security, and data. Our audit work focused on high risk management areas specific to MPDR including contract and system management, security, data integrity, and the extent data is used to identify possible misuse or diversion of prescription medications.

*(continued on back)*

## Results

Based on our work, we identified that since the legislature assigned registry management to the board of pharmacy, further planning and direction have not been pursued to identify the resources needed to maintain MPDR and effectively use the data within the registry for patient safety. Our work identified best practices and state and federal requirements that are not being met. Our audit recommends the following improvements:

- ◆ Developing a security plan and user management procedures to ensure personal health information maintained in MPDR is secure.
- ◆ Enhancing MPDR data integrity and reliability to better address prescription misuse and diversion, and the overall usefulness of the registry.
- ◆ Prioritizing project and contract management over MPDR to ensure the registry is properly operational.
- ◆ Analyzing and soliciting shared resources for project, contract, and security management.

Recommendation Concurrence	
Concur	9
Partially Concur	0
Do Not Concur	0
<b>Source: Agency audit response included in final report.</b>	

For a complete copy of the report (18DP-01) or for further information, contact the Legislative Audit Division at 406-444-3122; e-mail to [lad@mt.gov](mailto:lad@mt.gov); or check the web site at <https://leg.mt.gov/lad/audit-reports>  
 Report Fraud, Waste, and Abuse to the Legislative Auditor's FRAUD HOTLINE  
 Call toll-free 1-800-222-4446, or e-mail [LADHotline@mt.gov](mailto:LADHotline@mt.gov).

# Chapter I – Introduction and Background

## **Introduction**

The Montana Department of Public Health and Human Services reported drug overdose deaths are on the rise nationally and that it is the third leading cause of injury-related deaths in Montana. However, in Montana the number of related prescription drug overdose deaths is decreasing. According to the National Institute on Drug Abuse, Montana saw a rate of 4.2 deaths per 100,000 persons in 2016. While this is down from a high of 9.4 per 100,000 persons in 2006, there were still 42 opioid-related overdose deaths in Montana in 2016. Furthermore, Montana is still dealing with a significant rate of drug addiction. According to the Montana Department of Justice, 1 in 10 Montanans were dependent on or abusing drugs, including prescription medications, in 2017.

The Montana Prescription Drug Registry (MPDR) was authorized by the Montana Legislature in 2011 (§37-7-15, MCA) and became functional in November 2012. It serves as an online tool to provide a list of controlled substance prescriptions to health care providers, and help improve patient care and safety. MPDR is the only source of consolidated prescription drug dispensing data within the state, so it also acts as a powerful tool to help identify cases in which prescription medications are potentially being misused or inappropriately dispensed to the public.

## **Background**

Chapter 241 of the 2011 Legislative Session created the prescription drug registry. Initially, MPDR was to be administered by the Department of Justice (DOJ). However, because of privacy concerns surrounding personal health information (PHI), the registry oversight was instead allocated to the Board of Pharmacy (board). The bill created a set of statutes that required the board to establish and maintain a prescription drug registry for the purpose of improving patient safety. This includes electronically collecting information on prescription drug orders involving controlled substances, protecting confidentiality of the data, and disseminating information for:

- ♦ The review of possible misuse and diversion of controlled substances prescribed and dispensed to a patient.
- ♦ Public educational and health research.
- ♦ Law enforcement investigations.

The Department of Labor and Industry (DLI) administers this board through its Business Services Division (division). The division provides administrative services such as equipment and supplies. The board consists of seven members appointed by

the governor and is responsible for oversight of pharmacists and pharmacies around the state. Services provided by the department to the board include correspondence with licensees, processing and issuing license applications, organizing meetings, and maintaining the MPDR. The board has one full-time administrative specialist managing MPDR for the board.

Any technical work related to MPDR is done by a state contracted vendor. The vendor is approved by the State Information Technology Services Division (SITSD) through a term contract. The board developed a work order under this term contract for the development, hosting, and maintenance of MPDR in 2011. The same vendor currently maintains the technical aspects of the registry and assists the board with technical queries such as problems with registration, data submissions, rejections, and errors. Since inception, the registry has added the following functionalities:

- ◆ **Prescription data sharing:** Allows prescription drug data to be shared with other states that have prescription drug registries.
- ◆ **Pharmacy audit submission reports:** Track pharmacies' prescription drug report submissions.
- ◆ **Searching within registry:** Allows users to search for patient information.
- ◆ **Prescribers and pharmacists can delegate search authority:** These users can delegate their access to other medical professionals.
- ◆ **Searches can be traced and tracked:** Allows patients to see who has searched their record.
- ◆ **Law enforcement reports:** Pursuant to a subpoena, report on prescription data provided to law enforcement.
- ◆ **Statistical reports:** Provide registration and use statistics.
- ◆ **Error reports:** Provide a list of errors in a pharmacy submitted report.

## **MPDR Funding and Costs**

To date, the department has spent \$1,888,645 on the registry, which includes initial planning, development, maintenance, and operational expenditures. According to the board, the table on page 3 displays funding, income, and expenses related to the registry since 2012.

Table 1  
**MPDR Funding and Costs**

	Grant Funds Awarded	MPDR Fees Collected	Total MPDR Income	MPDR Expense Total
FY2012	\$397,521	\$0	\$379,521	\$276,199
FY2013	\$0	\$63,480	\$63,480	\$280,955
FY2014	\$376,137	\$96,600	\$472,737	\$215,670
FY2015	\$0	\$23,151	\$23,151	\$114,442
FY2016	\$364,304	\$193,040	\$557,344	\$306,392
FY2017	\$0	\$247,260	\$247,260	\$428,013
FY2018	\$0	\$220,410	\$220,410	\$266,973
<b>Totals</b>	<b>\$1,137,962</b>	<b>\$843,941</b>	<b>\$1,981,903</b>	<b>\$1,888,645</b>

**Source: Compiled by Legislative Audit Division from board records.**

Prior to MPDR implementation, the Montana Board of Crime Control (MBCC) was awarded a \$398,000 grant for the creation of a prescription drug monitoring program to reduce the misuse and abuse of prescription drugs and aid investigations of pharmaceutical crime for Montana. The grant was awarded through the US Department of Justice and facilitated by the MBCC. Because the registry was allocated to the board, MBCC distributed the grant funds to the board.

MPDR is also funded by prescriber and pharmacy license fees. All Montana licensees who are authorized to prescribe or dispense controlled substances pay an annual fee of \$30. This fee is collected during the license renewal process and is paid by pharmacists, doctors, physician assistants, dentists, podiatrists, advanced practice registered nurses, optometrists, and naturopathic physicians.

## **MPDR Data**

Controlled substances are drugs required to be dispensed only under a physician's prescription. These drugs have high risk of addiction, abuse, and death, as well as potential for trafficking by illegal means. Controlled substances are classified under a schedule rating shown in Table 2 (see page 4), where Schedule I is illegal illicit drugs such as methamphetamine, heroin, and crack cocaine and Schedule V have low potential for abuse. Schedule I drugs are not included in the registry because they are illegal and should not be dispensed. Schedule II-V drugs dispensed to humans or animals are submitted to the registry.

Table 2  
**Prescription Drug Schedule Ratings**

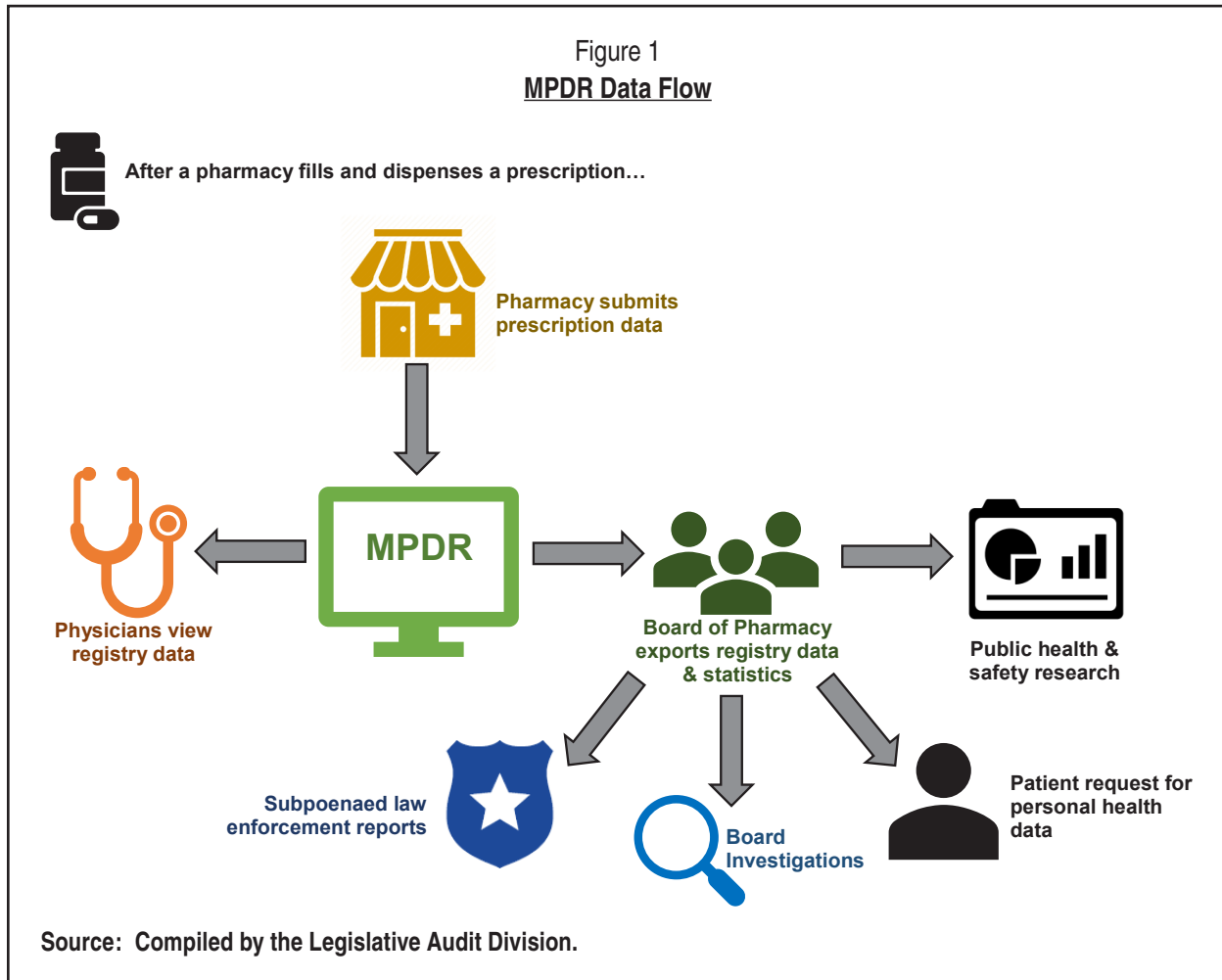
Schedule	Description
I	<b>Illegal</b> Drugs
II	<b>High potential</b> for abuse, with use potentially leading to severe psychological or physical dependence
III	<b>Moderate to low potential</b> for physical or psychological dependence; abuse potential is less than Schedule II but more than Schedule IV
IV	<b>Low potential</b> for abuse and <b>low risk</b> of dependence
V	<b>Lower potential for abuse than Schedule IV</b> and consist of preparations containing limited quantities of certain narcotics, generally used for antidiarrheal, antitussive, and analgesic purposes

**Source:** Compiled by Legislative Audit Division using information obtained from Montana Code Annotated, US Drug Enforcement Agency, and Center for Disease Control.

Prescription drug registries like MPDR have been implemented in every state to track controlled substance prescriptions. The main purpose of MPDR is to collect data related to dispensed prescriptions for Schedules II–V. The data submitted to the registry contains patient personal health information (PHI), prescriber name, pharmacy information, and dispensing data. Dispensing data in MPDR includes date written, date filled, drug name, and quantity dispensed. Prescription data is considered PHI because it includes patient name, date of birth, contact information, and prescription health history.

## MPDR Submission Process and Use

Pharmacies are responsible for submitting all controlled substances dispensed to patients. Figure 1 (see page 5) shows that once data is submitted by the pharmacy, prescription information is available to five types of stakeholders: the patient by request, patient providers through searches, board compliance investigators, public health and safety researchers, and law enforcement when investigating prescription drug related crimes via subpoena. Chapter 89 of the 2019 Legislative Session requires prescribers or their delegates to review a patient's records in the MPDR prior to prescribing certain substances; however, during audit fieldwork the law did not have this requirement.



All licensed pharmacies are required to report dispensed controlled substances within one business day. Data submission in to the registry can occur several ways:

- ♦ **Secure File Transfer Protocol Connection:** Secure File Transfer Protocol is a nationally accepted method for electronic transmission of protected health information. This is an automated electronic connection between a pharmacy's computer and the MPDR. This method can be used for uploading data files and for submitting Zero Reports. Zero Reports are submitted by pharmacies that have not dispensed any Schedule II-V controlled substances within a defined time frame.
- ♦ **Manually Upload Files:** Pharmacies save all prescription drug information for reporting period into one file and log into the registry portal to upload the file.
- ♦ **Manual Data Entry:** Pharmacies log into the registry portal and manually enter the individual information, like patient name, prescription number, and days of supply.

Many pharmacies choose to coordinate with software vendors to submit the reports discussed above. This is accomplished either directly with the pharmacy's software vendor or through the pharmacy's corporate office. Pharmacies also have the option to directly submit the data into the registry, although this typically occurs at locally owned pharmacies or hospital pharmacies.

## **The Future of MPDR**

The board is currently developing a request for proposal (RFP) for a new registry. The board indicated there are many systems already being used by other states that could provide effective and sustainable functionality as prescription drug registries expand nationally. The board feels these commercial off-the-shelf systems will be more adaptable to changes than the current in-house developed registry. The division requested one-time HB 2 funding from the 2019 Legislature for development and implementation of the new registry. Consequently, new development or initiatives are on hold in the current system until a new vendor/registry is awarded through the RFP.

## **Audit Scope**

While our audit focused on the board's activities related to maintaining MPDR, we also reviewed the support activities from DLI Technology Services Division (TSD) and SITSD. This audit focused primarily on three areas:

1. MPDR contract and project management by the board and the role of SITSD relative to the term contract. We examined 2012 to 2018 vendor payment data, services delivered, and contractual obligations.
2. Security over information within the registry. Since MPDR data is hosted with the vendor, we looked at how the board assures security of the registry through coordination with SITSD and user management practices. This included reviewing user access and employment history of individuals with access to the registry. The time frame for this review was January through June 2017.
3. Data integrity and utility. To determine the reliability and completeness of the registry, we reviewed and tested prescription drug registry data for 2016-17. Testing also included identification of potential prescription drug misuse and abuse.

## **Scope Limitation**

Audit standards require us to clearly specify any scope limitations within our report. Scope limitations include actions taken by the auditee that limit our ability to complete audit work punctually and rely on evidence provided. We experienced an eight-month delay in the department providing us access to MPDR, which contained all pertinent information needed to complete our audit. We initially received access to search individual patients through the online portal, however, our work required us to



perform a mass data analysis. We requested this access in January 2018 and did not receive access until August 2018. The Legislative Audit Division (LAD) has legal access to personal health information through Title 5, Chapter 13, MCA, (Legislative Audit Act) and federal law (HIPAA). Despite this, the department denied access based on concerns over PHI contained in the registry, and whether LAD had legal authority to access this information. In August 2018, we signed a memorandum of understanding with the department agreeing to provide us access to MPDR and ensuring we would keep MPDR data secure. While the department is expected to perform due diligence in ensuring security of PHI, we believe delaying access for eight months was excessive and unnecessary.

Delays of this nature impact our ability to effectively develop audit scope and methodologies, increases risks of data being changed or altered, and results in untimely completion of our audit work. The delay we experienced during the audit resulted in reporting our findings after the 2019 Legislative Session. If we had received the information in a timely manner, our audit report would have been ready for 2019 Legislative Session.

We also experienced constraints to our audit approach and analysis due to limited reliability of MPDR data. This included missing data, nonsensical data, and inconsistencies in data reporting.

## **Audit Objectives**

We developed the following audit objectives related to MPDR:

1. Determine if the Board of Pharmacy is managing the vendor contract by ensuring contractual obligations are met.
2. Determine if the Board of Pharmacy is governing and defining security over personal health information.
3. Determine if the Board of Pharmacy is ensuring protection of personal health information through user management procedures.
4. Determine if the Board of Pharmacy is ensuring integrity of registry data and if that data is being used to effectively prevent misuse and diversion.

## **Audit Methodologies**

Steps taken to answer our objectives included:

- ♦ Analyzed MPDR work orders, change requests, and enhancements to compile contract payment data and identify service delivery dates and payment dates.
- ♦ Compared Project Management Body of Knowledge national standards and state requirements to board's project and contract management practices.

- ♦ Interviewed MPDR board staff to review contract information, daily tasks and processes, and overall security over MPDR.
- ♦ Researched and reviewed vendor security reports, state security policy, and coordination of responsibilities over MPDR security.
- ♦ Interviewed Department of Labor and Industry and State Information Technology Services Division staff to determine security measures and procedures.
- ♦ Researched and reviewed federal HIPAA rules and guidelines and compared current board practices to HIPAA standards.
- ♦ Compared security industry standards to MPDR user management policy and procedure.
- ♦ Interviewed MPDR administrative staff, board staff, and registry stakeholders such as Department of Justice and Department of Public Health and Human Services staff to determine effectiveness and accuracy of MPDR data.
- ♦ Observed MPDR staff to verify manual work conducted.
- ♦ Researched, identified, developed, and tested MPDR data integrity tests including completeness of the data, accuracy of the data, and usefulness of the data.
- ♦ Researched and compiled best practices, industry standards, state rule, state law, and federal law to define misuse and diversion activity and thresholds.
- ♦ Conducted MPDR data analysis testing for potential abusive activity for calendar year 2016 through 2017.
- ♦ Compared board's management over MPDR and use of registry data to best practices and recommendations from similar states and national standards.

## **Report Contents**

The remainder of this report includes additional background and details of our findings, conclusions, and recommendations. It is organized in the following manner:

- ♦ Chapter II addresses management practices and resources allocated to the registry at the time of audit fieldwork.
- ♦ Chapter III discusses the registry's security management of sensitive data and deficiencies in user access control.
- ♦ Chapter IV presents information regarding the reliability of prescription drug data.
- ♦ Chapter V discusses the effectiveness of the data in improving patient safety and addressing misuse and diversion.
- ♦ Chapter VI provides recommendations for ensuring the future of the registry is successful.

## **Chapter II –The Board of Pharmacy Needs to Improve Montana Prescription Drug Registry Project and Contract Management Oversight**

### **Introduction**

Our first objective was to determine if the Board of Pharmacy (board) is actively managing the Montana Prescription Drug Registry (MPDR) vendor contract and ensuring obligations are met. Sound contract and project management ensures this happens by establishing consistent practices that govern system development and oversight of third party contracts. These management elements are important for ensuring project obligations are met, payments are executed properly, and MPDR is providing reliable information. Without these oversight elements, the board increases risks such as overpayment and untimely delivery. This leaves less time and resources to address the intent of the registry—improving patient safety by reducing the risk of overdose deaths and substance abuse and addiction.

This chapter discusses our review of MPDR work orders, the board's payments to the vendor, the delivered functionality of the registry, and contract and project management. Through this work we found the board did not follow established management procedures to ensure contractual obligations were met specific to MPDR. The following sections address actions the board should take to ensure compliance with the contract, state law, and state policy and to increase its capability to better manage the registry.

### **Multiple Standards Exist to Ensure Funds Are Spent Effectively**

Due to the importance of mitigating information technology project and contract management risks, there are multiple policies, rules, and laws addressing quality assurance. The Department of Administration's State Procurement Bureau (SPB) and State Information Technology Services Division (SITSD) provide guidelines and policies to ensure agencies are consistent in standards and practices. State procurement rules, state law, and policy document quality assurance reviews be part of agency contract management procedures and incorporate corrective actions of vendors who are not meeting contractual obligations. For example, vendors not delivering required services or meeting required timelines can have corrective actions taken, including cancellation of the contract. SITSD also requires alignment with project and contract management standards outlined in project management national standards. The contract should enforce obligations outlining assurance and monitoring activities on a scheduled basis. This not only provides assurances over meeting the requirements of

the system, but also provides transparency to funding sources, registry stakeholders, and users. Without these quality assurance measures, neither party can identify poor vendor performance or contractual obligations.

MPDR development was funded by a federal grant which provided an opportunity to enhance the state's capacity to collect and analyze controlled substances data through a centralized database. The grant was facilitated through the Montana Board of Crime Control (MBCC). According to MBCC, the grant does not contain explicit language outlining payment terms such as requiring delivered and approved services prior to payment, but they indicated it must align with state procurement and contract management standards.

### **Contract Management and MPDR Development** **Weaknesses Occurred Throughout System** **Implementation and Maintenance**

Our work reviewed the various contracts, obligations, and responsibilities involved in managing MPDR. This included the term contract managed by SITSD, system work orders developed by the board and Department of Labor and Industry (DLI), and how the responsibilities and relationship are structured between SITSD, DLI, the board, and SPB to oversee the system and manage the work order specific to MPDR. Through interviews and examining documentation, we found the board did not take an active role in addressing vendor issues nor did it assure the work order contained required language to achieve a successful implementation and future maintenance. The specific issues we identified within oversight and contract management are discussed in the following sections.

#### **Work Order Does Not Contain Required Language**

SPB created a Statement of Work (equivalent to work order) template in 2008 that contains detailed language regarding responsibilities, hours and rates, and completion criteria to support state agencies' ability to manage contracts. However, after comparing this template to the MPDR work order, it was clear the SPB template was not used for MPDR. Because current board staff were not involved with registry development, they did not know the reason the template was not used for development of the registry.

The MPDR work order outlined the deliverables needed to produce a functioning registry. However, it lacked specific language regarding board approvals, payment terms, and roles and responsibilities. We found no other plans or documents defining these required elements such as a responsibility document outlining vendor, security, and management responsibilities which is found in all system development projects.

Without defined approval criteria and payment schedules, payments can be made without receiving working services, regardless if signature approvals are provided. So, while the board approves functionality and pays for it, there is no assurance the functionality is useable because what is useable is not clearly defined.

### **Grant Funded Payments Were Made Prior to Deliverables Being Met**

We identified issues when reviewing the work order and attempting to correlate subsequent system requests for functionality and payments made to the vendor. We identified several MPDR functions that the board paid for prior to implementation and that continue to have limited functionality. Since the work order does not indicate the dollar amount for developing and implementing each area of MPDR functionality, we could not identify an exact amount of money paid prior to system features being usable.

For instance, Compliance Audit Reports (CARs) are used by the board to monitor and ensure pharmacies are properly reporting prescribed medications. These reports identify pharmacies not reporting data or fixing data errors. These audits are important because the process identifies pharmacies that are not in compliance with reporting requirements. Pharmacy reporting was paid for as part of the original work order payment, but an estimate of time, resources, and cost specific to CAR functionality was not specified in the original work order. These reports are not functioning as expected and require extensive review, recalculation, and data verifications, which creates unnecessary time allocated to pharmacy compliance audits. These reports should be reliable enough to complete the process in a week or two; however, the last complete audit done in 2018 took three months.

We identified other areas of MPDR functionality the board paid for but are unreliable or not working as intended. Subsequent enhancement and change requests indicate that a minimum of \$60,520 was paid to the vendor for this functionality. Examples of contractual issues include:

- ♦ Law enforcement reports will time out and crash the system if there are large volumes of data within the reports, despite functionality being fully paid for. Law enforcement reports contain information related to potential criminal activity and are important for ensuring this activity is identified. Currently, the board must coordinate with the vendor to run reports. Although this work-around is providing the board what it needs, the board paid for this functionality to be in the system.
- ♦ Data transfer to the Department of Public Health and Human Services (DPHHS) was delayed until May 2018. DPHHS uses this data to conduct research and provide findings to the state to address substance abuse in

Montana. The board paid for the transfer in January 2018, but DPHHS did not receive the data until May 2018. This means the board paid for a service prior to the service being delivered.

- ◆ Merge patient functionality is included in the original work order, however according to board officials this functionality was not further discussed with the vendor prior to being implemented. Now the functionality is unreliable and not used. Merge patient functionality is supposed to identify duplicate patients in the registry and allow the department to merge the patients' records in the registry. This is an important functionality in addressing data integrity by ensuring a unique ID is assigned to individual patients.

After discussing these issues with the board and MBCC in March 2018, MBCC extended the grant deadline to May 2018 to allow the board to complete the functionality. Because no acceptance criterion was established, the board approved all functionality funded by the grant by May 2018 even though certain functions, like CARs and merging patient records, are still unreliable. The board's actions were not consistent with best practices and have led to paying for services prior to delivery of a useful, complete product.

## **Delayed System Implementation and Missing Documentation Identified**

When reviewing work order and requests for additional functionality and enhancements, we also identified several instances when the required deliverable timelines were shifted and extended. Official documentation surrounding these extensions did not exist. After we discussed the timeline issues with board officials, they created enforced timelines for the vendor.

There were 34 change and enhancement requests made by the board to the vendor between MPDR implementation in 2012 and March 2018. We identified several timeline discrepancies, missing documentation, and improper signatures. We also found it took two years to develop and implement stakeholder-requested user access.

Contract management standards specifically require documentation and approvals for these types of changes and decisions. While examining the requests, we identified multiple requests with the following issues:

- ◆ Final acceptance documented on the request was prior to implementation of the specified functionality.
- ◆ No documented approval from executives.
- ◆ No expected delivery date established for the functionality.
- ◆ Functionality that was implemented after expected delivery date.
- ◆ No documentation of approvals or discussion for these timeline changes.

The following table quantifies the issues we identified.

Table 3 <b><u>System Request Analysis Results</u></b>		
<b>Error Type</b>	<b>System Requests in Error</b>	<b>% of Total Reviewed</b>
Final Acceptance <b><u>Before</u></b> Implementation	14	82%
<b><u>No</u></b> Documented Approval	17	50%
<b><u>No</u></b> Documented Expected Delivery Date	17	50%
Implemented <b><u>After</u></b> Expected Delivery Date	11	32%
<b><u>No</u></b> Documentation of Timeline Changes	33	97%
<b>Source: Compiled by the Legislative Audit Division.</b>		

Project management standards describe clear and precise approval criteria outline stages of final approval. They also describe criteria that should be met before the deliverable can be considered complete. Most of the documentation we reviewed omitted information, such as changes in timelines, and was missing signatures from vendor, board, and SITSD. Not only does the statewide term contract indicate all signatures must be present before moving to the next stage, but standards also emphasize documented approvals for each step and decision.

### **Minimal Communication and Accountability Contributed to Problems**

In the term contract, specific language outlines the state's responsibility for contract oversight. It indicates the state Chief Information Officer (CIO), or office of SITSD, may perform contract oversight activities. These include identification, analysis, resolution, and prevention of deficiencies that occur within performance of contract obligations. It is the board's responsibility to request support from SITSD, but the board did not seek this assistance to help resolve issues related to MPDR development and functionality. The CIO and SITSD had limited involvement in overseeing the MPDR contract. However, if the board had coordinated with either the CIO or SITSD, staff could have assisted the board in resolving issues and ensuring payments to the vendor were not made until issues were resolved.

As part of managing vendor performance, weekly progress meetings between the vendor and SITSD are required to occur. However, we found these meetings did not consistently take place. Work order priorities, including those for MPDR, are one topic specifically required by the term contract to be discussed during these meetings. These



discussions can also help address performance issues, but issues related to MPDR development and functionality were not brought forward. In addition to inconsistent meetings between SITSD and the vendor occurring, we found the board did not have presence at these meetings when they did occur. Without board presence in these meetings or communication with SITSD, issues related to MPDR were not addressed.

We determined the MPDR term contract and subsequent work orders split contract management between SITSD and the board. Without defined responsibilities, it is not clear who is ultimately responsible for MPDR contract management activities, such as communication and oversight. SITSD indicated it relies on the board to communicate issues. Conversely, the board believes SITSD is responsible for managing contract obligations with the vendor. The unclear definition of responsibility and communication between roles resulted in poor contract and project management of MPDR.

### **MPDR Requires Established Procedures and Responsibilities**

While oversight and monitoring are SITSD's role within the term contract, the board is responsible for ensuring oversight and monitoring of MPDR. The board is responsible for communicating progress and issues to SITSD, so the problems can be discussed and addressed by all parties. It is important the board coordinates with SITSD. The board is also responsible for ensuring the work order is managed according to contract and project management definitions. However, because responsibilities are not defined due to the missing language required in work order templates, none of the entities are held accountable to meet contractual obligations.

Management over MPDR is important because it ensures the completeness of functionality as well as providing clear milestones and deliverables that align with payments and business requirements. With defined relationships and consistent management, both with the work orders and with the term contract, the following weaknesses with MPDR functionality and development can be mitigated:

- ◆ Undefined payment terms and timelines.
- ◆ Nonworking functionality.
- ◆ Compliance with contractual terms and risk mitigation, including contractual breaches, financial penalties, and receiving services that lack quality.
- ◆ Increased time and effort to support and maintain the registry.

The board is currently developing an RFP to implement a new prescription drug registry. Following formalized procedures for effective MPDR contract management



and contract development are necessary to ensure the success of future contracts and projects. The department and board officials indicate they are now following contract management processes and procedures as well as using department resources.

---

#### **RECOMMENDATION #1**

*We recommend the Department of Labor and Industry regularly coordinate with the Board of Pharmacy to establish, follow, and enforce project and contract management procedures to include:*

- A. Definitions for communication expectations and responsibilities,*
  - B. Management of project changes and enhancements, and*
  - C. Adherence to state procurement standards.*
- 

### **Data Destruction Was Not Timely**

Data destruction of information contained within MPDR is specifically required by §37-7-1508, MCA. Statute requires sensitive personal health information (PHI) collected for the registry to be destroyed after three years. Destroying data older than three years old allows the board to lower its risk of large amounts of data being stolen.

MPDR was required to have an automated data destruction function developed to comply with data destruction and retention laws. During our work, we found this function had not been implemented and was a year overdue from when it was supposed to be operational. This functionality was deprioritized by the board and the vendor to get other MPDR functions such as patient searches and online registration finished first. In January 2019, two years after the initial request for functionality, the board implemented the data destruction functionality. There is now an automated process to remove all data older than three years. According to the board, this process runs automatically at the end of every month.

While this addresses MPDR data controlled by the board, DPHHS epidemiologists also hold a one-time copy of MPDR data to identify statistics and trends in drug prescriptions for educational and public research purposes. However, because data destruction was not implemented when data was shared, DPHHS received data from the inception of MPDR in 2012 until the end of 2018. A Memorandum of Understanding (MOU) was signed between DPHHS and the board to ensure protection and use of the data, but it does not contain a provision that PHI information will be destroyed or de-identified after three years. The MOU only states that data received will be archived by DPHHS.

While DPHHS needs large data sets to analyze long-term trends, sending identifiable patient data does not align with MPDR data destruction and retention statute. It increases the impact of a data breach if one were to occur within DPHHS. The board needs to work with DPHHS to destroy or de-identify data over three years old. Having a data destruction and retention plan will ensure timely destruction in accordance with statute. A thorough plan would include any shared data with authorized entities and would minimize the effect of any potential security breaches.

---

**RECOMMENDATION #2**

*We recommend the Department of Labor and Industry and the Board of Pharmacy:*

- A. Work with Department of Public Health and Human Services to immediately and permanently destroy or de-identify prescription drug data older than three years.*
  - B. Develop a data destruction and retention plan to ensure destruction of shared prescription drug data.*
-

## Chapter III – Security Governance and User Management

### Introduction

The Montana Prescription Drug Registry (MPDR) contains personal health information (PHI) such as patient names, birthdates, and prescribed medication, which is classified as confidential information. If this data is not protected, the risk of personal medical records and personal health information (PHI) being stolen or shared with unauthorized individuals increases.

Our second objective was to determine if the MPDR has efficient governance over system security to prevent unauthorized access to PHI. This chapter discusses the current security measures the Board of Pharmacy (board) is taking to protect PHI through assuring security of the system and managing user access to system data. It explains our review of current security procedures relative to those required by federal law and state policy. We address the need for the board to improve security by complying with these laws and establishing more comprehensive user management procedures.

### MPDR Security Requirements

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is the federal law designed to provide privacy standards to protect patients' medical records and other health information. HIPAA laws exist to ensure private health information is protected, including prescription drug information. Security rules exist within HIPAA to ensure the confidentiality, integrity, and security over PHI. Similar to a covered entity under HIPAA, the board's management of MPDR must be consistent with privacy provisions. These rules include standards that relate to PHI. The rules encompass information that is created, received, used, or maintained, and require the following safeguards:

- ♦ **Administrative:** This includes administrative actions (referred to as safeguards), and policies and procedures to manage selection, development, implementation, and maintenance of security measures to protect PHI. One important piece of administrative safeguards is a security plan that includes conducting comprehensive risk assessments.
- ♦ **Physical:** Physical measures, policies, and procedures protect the board's PHI information systems and related buildings and equipment from natural and environmental hazards, and unauthorized intrusion. Examples of these measures address facility and work station security.
- ♦ **Technical:** These safeguards are directed at technology and the policy and procedures for its use that protect PHI and control access to it. Examples of

technical safeguards include ensuring data are not improperly altered and access to the data is controlled.

Along with federal laws, security standards required for all systems within Montana, no matter what data are involved, also need to be met. This includes more detailed requirements, specifically in user management, that were used for our audit.

### **Current Security Assurances Are Limited**

Because MPDR data is hosted by the vendor, it was agreed the board would rely on the vendor's security measures. As part of the assurance over the security of the vendor's data center and services, the vendor provides yearly reports to the State Information Technology Services Division (SITSD). SITSD reviews these reports as part of managing the term contract with this vendor. According to SITSD, they discuss various reports monthly with the vendor to address security. We reviewed two of these reports in-depth and identified that MPDR is not within the scope of these reports. We also determined that HIPAA security safeguards were not assured through the other security reports provided to SITSD at the time of our review. Further discussion with SITSD indicated that third-party assurances were going to change in 2018 to provide HIPAA assurances.

Requiring the vendor to provide these reports gives assurance over their management of the registry; however, the department and board need to take additional steps to comply with HIPAA security rules. Through comparison of best practices and HIPAA laws to board procedures, we identified administrative and technical safeguards such as risk analysis and user management procedures that were not being conducted. By implementing these procedures, the board will be able to establish necessary security over PHI as well as update security protocols as risks evolve. For example, the use of multi-factor authentication to view or access PHI is not required by HIPAA. However, guidelines within HIPAA security rules provide further specifications like this for consideration during risk analysis. If the risk analysis points out vulnerabilities in data transfer, it recommends implementing multi-factor authentication.

### **Security Governance and Responsibility Is Undefined**

The Board of Pharmacy (board), the Department of Labor and Industry (DLI), and SITSD understand the importance of security over the vendor and the system; however, MPDR is unique in that it has multiple entities with a role in securing PHI. Because of this, thorough understanding of how this structure provides all the necessary security and who is responsible for various security measures is paramount. The term contract and MPDR statement of work do not contain language regarding the measures taken to protect PHI. We did not identify clear documentation of system security governance, details for security responsibilities, or established procedures to assure security. This

leaves each entity managing its own security measures with limited understanding of how it all coordinates to ensure HIPAA and state policy compliance:

- ◆ DLI's Technical Services Division (TSD) manages security services such as security awareness and training for board staff with general policies used for all DLI systems. However, those policies and procedures do not address HIPAA-required procedures needed for PHI within MPDR.
- ◆ The board manages administrative procedures to ensure security like user access and data sharing. It does not have complete system security policies or procedures that meet administrative safeguards required by HIPAA and state policy.
- ◆ SITSD manages vendor level security through SOC reports, but these reports do not provide complete HIPAA assurance.

Responsibilities over the governance of the security of MPDR include ensuring security services are provided for protection over PHI and developing a security plan. A security plan specific to MPDR would define these security measures and how they are coordinated, identify gaps between individual security procedures, and clearly state who is responsible for each security measure.

### **HIPAA Security Rule Is Not Fully Implemented Due to Incomplete Security Management**

Without clear responsibilities and knowledge of security standards, the risk for noncompliance and unauthorized access to data is increased. We found security procedures like those required by HIPAA have not been prioritized due to a lack of security planning and governance related to MPDR. This includes developing clear lines of responsibilities between the board, DLI, and SITSD, and performing ongoing risk assessments. Governance would ensure that all security measures work in coordination to meet all applicable state and federal laws. The board needs to establish a security plan and security governance specific to MPDR, so any unique situations can be addressed to reduce these risks.

---

#### **RECOMMENDATION #3**

*We recommend the Department of Labor and Industry work with the Board of Pharmacy to develop a governance structure and implement a security plan for the Montana Prescription Drug Registry that:*

- A. *Defines the security responsibilities,*
  - B. *Requires annual risk assessments,*
  - C. *Mitigates significant security risks as identified, and*
  - D. *Ensures compliance with HIPAA security rules.*
-

## **User Management Is Crucial for Securing Personal Health Information**

Technical safeguards are required through HIPAA security rules and are important in ensuring PHI is not accessed by unauthorized individuals. One of those safeguards is user management. User management controls what type of access system users have and limits what data they can see. It also is a process for consistently managing users by thorough reviews of system access and activity. We found the board needs to improve user management practices to meet both HIPAA technical safeguards and user management best practices.

### **MPDR User Access Structure**

To gain access to MPDR, the user needs to register with the board. Various user types exist within the system. These include:

- ♦ **Registered Users:** Registered users are primarily medical licensees with the authority to prescribe medications in Montana. Self-study training courses are available to registered users regarding system protocols. After reviewing training documents, users register with the board, which allows them to search the database. Registration requires name, date of birth, medical license information, and contact information. Once registered, users are required to create a secure account to access MPDR on the state network. During fieldwork in April 2018, the board reported MPDR had 3,494 registered users.
- ♦ **Delegated Users:** Registered users also have the option to delegate their authority to view patient information within MPDR. Delegates can be a variety of users, such as nurses or pharmacy assistants; however, they are not required to be licensed healthcare workers. During fieldwork in June 2018, the board reported 1,211 active delegates.
- ♦ **Administrative Users:** These users are both board staff and vendor staff. Vendor staff must sign and return an agreement outlining acceptable use of the system prior to obtaining access. The vendor primarily accesses MPDR for customer service assistance, such as help desk tickets, verifying key functionalities are working, and troubleshooting submissions. Administrative users can search patient and provider histories, review supervisor/delegate search history, and establish users within the system. During fieldwork in May 2018, the board reported eight administrative and other users, such as representatives from Department of Public Health and Human Services.

### **User Management Procedures Need Improvement**

The board established procedures for granting access to MPDR. This includes approval of initial access for only registered users and controlling their access through systematic verification of license status when at log-in, and by monitoring complaints of inappropriate use. If the board determines user access should be revoked due

to a complaint, such as a violation in prescribing laws, the board provides written notification to the user's supervising board explaining why access should be revoked. It is up to the supervising board to decide if access should be revoked. We did not find any instances or complaints being received and access being revoked. It is unclear what constitutes a complaint serious enough to revoke access.

Through interviews with board staff and review of these user management policies and procedures, we identified multiple issues that increase the risk of unauthorized access. These include:

- ◆ Reviews of administrative and delegated users are not conducted consistently, which poses a significant MPDR security risk. Currently, the board relies on the contracted vendor to self-report user access changes. To manage delegated access, the system establishes a required review date when registered users will be reminded to review their delegates' access, or it will be terminated. However, registered users can change these review dates, which bypasses the control. Without having an independent scheduled review of all users, the registry data could be accessed by unauthorized users. State security policy and TSD policy requires annual reviews be conducted to mitigate these types of risks for all systems.
- ◆ Board MPDR access policy requires detailed audit documentation outlining vendor administrative staff use, but we found this documentation does not exist. Vendor access needs significant control because it not only allows access to view patient data, but also view and modify all data and system code on servers hosted with the vendor. To prevent unauthorized activity, the board requires the vendor to sign an agreement, but it does not enforce security by monitoring and reviewing vendor access consistently. Access and activity reviews need to include vendor staff and documentation of these reviews should be maintained.
- ◆ Board staff are responsible for reviewing all MPDR users, including administrative users who have access to view all patient data due to the various statewide customer support needs, data quality procedures, and pharmacy audits. However, we found that in practice, responsibility for reviewing all MPDR users is left to one board staff member. This person also has administrative access, so a conflict of interest exists because they are also responsible for monitoring their own access. According to industry standards, access control prevents users from having all the authority or information access, especially without review by another person to ensure this access is not misused.
- ◆ User access termination controls do not cover all users to ensure access is removed on a timely basis. Delegated users are not controlled by administrative staff but are self-governed by associated registered users. The board relies on a registered user's secure network account to expire for termination of delegated user access to MPDR, particularly if the registered user does not actively manage delegated user access. After 24 months of inactivity the secure network account is deactivated, but this does not deactivate the MPDR account. Consequently, this allows for two years of unauthorized



access to MPDR information. Relying on secure accounts to deactivate also does not address delegated users changing supervising providers. It is the previous manager's responsibility to remove access. Therefore, it is likely a delegate could be listed under two managers if the former manager did not terminate their relationship. In this instance, the user would still be active but would have access to specific patient information under the former manager that is no longer necessary.

## **Self-Governing Access Does Not Meet Best Practices**

Although registered users are responsible to self-govern, the board is responsible for ensuring user management is occurring, whether it be by board staff or supervising providers. Board staff, as "system owners", are accountable for making sure this information is protected and accessed by authorized individuals. Multiple key controls in user management criteria exist and it is the board's responsibility to ensure they are implemented to enforce MPDR security, manage conflicts of interest, and monitor user activity.

If users can access the system after terminating employment, the potential for illegal access to personal health information increases. Therefore, ongoing monitoring of user activity and ensuring access is appropriate is crucial to protecting MPDR data.

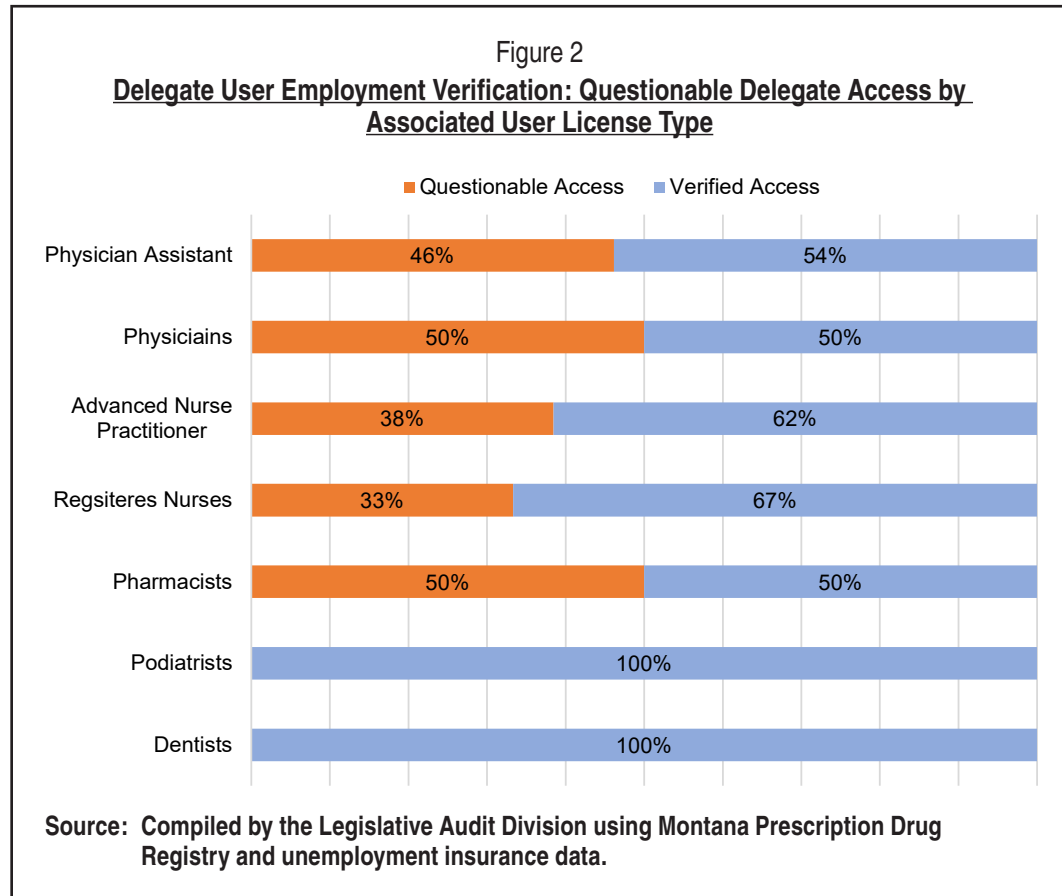
## **Current Access Controls Allow Unauthorized Access**

Since the board does not conduct user reviews, we reviewed a sample of active delegated MPDR users from various supervising provider license types, such as medical doctors who had delegated search authority to a nurse or technician. We compared unemployment insurance payroll records of delegated user employers with supervising provider employers to determine if the delegate user had been employed at the same organization as their supervisor. If a supervising provider was managing delegate access, the delegated user's employer would match in the payroll records maintained by the department.

We reviewed 56 delegate relationships that were active during the first quarter of 2018. These relationships related to seven different types of supervising providers: physician assistants, physicians, pharmacists, advanced nurse practitioners, dentists, registered nurses, and podiatrists. The delegated users for these supervising providers are generally office assistants, nurses, and technicians. Our audit work identified 24 delegates who were not employed under the same facility as their managing provider during the time their delegate relationship was active in the system. Board officials indicated there are instances where a delegate may not work in the same facility as the supervisor. Because



of this, these results may be valid exceptions. However, this test still provides insight to management of delegate relationships. These results are shown in the figure below.



Because we could not correlate employment for almost half of the delegate relationships reviewed, there is a probability that supervising providers are not managing delegate access as required. This increases the risk of unauthorized access, and is compounded by the reliance on an activity-based termination. If these users no longer need access to MPDR but the delegate relationship still allows them access, they may never be terminated if they log into the system through the secure network account to remain active. This control structure allows for an unauthorized user to have permanent access to PHI if the supervising provider has extended the user's access review date far enough. The relationship status between the delegate and supervising provider will not limit this access either if the supervising providers licensing status is inactive and he/she is blocked from using MPDR.

### **Board Has Not Prioritized User Management**

According to board officials, it trusted MPDR was working as needed with the current automated registration processes, which automatically verifies the license of a

supervising provider in the licensing database. Consequently, board officials placed a low priority on conducting and monitoring activity. Even though the job description of the board staff member requires these reviews to occur, other job duties have taken priority.

The board has relied on MPDR's automatic registration process to identify and remove unauthorized users when their license expires. However, this automated process only captures those with licenses, not delegates or administrative users. The board does not have an alternative process to monitor user access, so it is also not ensuring the removal process is working. Periodic manual reviews should be conducted to verify the automated process is terminating unnecessary user access as needed. It should also be conducted to ensure delegated users and administrative users are removed as needed. TSD policy requires reviews be conducted every six months. The board and DLI should develop a formal process to monitor and review user access and activity.

---

**RECOMMENDATION #4**

*We recommend the Department of Labor and Industry coordinate with the Board of Pharmacy to:*

- A. Establish a process to enforce review of Montana Prescription Drug Registry delegate users.*
  - B. Develop and implement procedures to review administrative and vendor user activity.*
-

# Chapter IV –Montana Prescription Drug Registry Data Reliability

## Introduction

Data integrity is the assurance of the accuracy and consistency of data and is crucial for the Montana Prescription Drug Registry (MPDR) to ensure patient safety and to monitor prescription drug use. This chapter addresses our third audit objective to determine if the Board of Pharmacy (board) ensures the integrity of registry data. Our work identified several concerns related to the reliability and accuracy of MPDR data. This included missing data, nonsensical data, and inconsistencies in data reporting. This chapter discusses these issues in more detail and presents recommendations to address weaknesses we identified.

## Reliable and Accurate Data Is Important for Several Reasons

MPDR having reliable and accurate data is important for several reasons, the most important being that accurate and reliable data helps ensure patient safety by ensuring prescription drugs are appropriately dispensed. There are also other reasons why data reliability is important for MPDR. These include:

- ♦ **Data sharing with other states and agencies:** Other state agencies use the data to track prescription drug use and develop initiatives to improve the safety of Montana citizens. Using the data enables other agencies to address prescription drug use problems around the state, such as the Department of Justice using the data in criminal investigations. The ability to share this data across state lines provides a more complete and accurate history if patients see doctors in multiple states.
- ♦ **Identification of improper prescribing and dispensing of prescription drugs:** Evidence of misuse and diversion includes suspicious patient activity (doctor shopping, pharmacy shopping) and suspicious prescriber activity (pill mills, prescribing dangerous combinations, violating prescribing laws). These instances can be found and addressed if the data is accurate and complete.

We reviewed current systematic and manual processes to verify MPDR data integrity. We obtained all registry data for calendar year 2016 and 2017 and examined 3.9 million prescription drug records. This included testing various data fields to evaluate the accuracy and reliability of MPDR prescription data, patient data, drug data, and pharmacy data.

Obtaining prescription drug data through MPDR is an important and significant step to help identify possible illegal prescribing and dispensing of prescription drugs to help

the state respond to widespread opioid use. However, we noted several improvements are needed to increase MPDR data reliability and how registry information can be used to address potential misuse and diversion of prescription drugs. According to §37-7-1502, MCA, the intent of the registry is to increase patient safety by reducing their risk of overdose and illegal use. Based on the weaknesses we identified with MPDR data, the registry has limited effectiveness in fulfilling this need.

### **Some Controls Exist for Correcting Errors**

Pharmacies that dispense controlled substances are required by law and rule to submit dispensing information of prescription drug orders to the board. A pharmacy can submit and modify information within MPDR and can only modify the information it submitted. Pharmacies can also remove prescriptions that it previously submitted from MPDR.

Some controls exist within MPDR to ensure the consistency of data submitted by pharmacies and entered into the registry, as required by §37-7-1503, MCA. There are simple checks and verifications that automatically occur when pharmacies or the pharmacy corporate office submit data. These verifications occur both for data that is manually entered and uploaded through manual uploads and for direct connections. The following describes these verifications intended to help improve accuracy of data that pharmacies enter into the registry.

**File and/or Record Rejection:** An uploaded file or record will not be loaded into MPDR if it does not meet the American Society for Automation in Pharmacy (ASAP) 4.1 requirements or layout. ASAP 4.1 is the national set of data standards that states must follow to ensure prescription drug information is consistent between all states. These standards ensure the minimum data fields are consistently formatted and included in reporting, so data can be easily shared between states. If a file or record is rejected, the format needs to be corrected, and the entire file or record must be resubmitted to the MPDR by close of the next business day. When a file or record is rejected, the data is not stored in MPDR until the pharmacy resubmits the information in the correct format.

**Error Messages Requiring Corrections:** An error message is sent to the submitter when a prescription is missing a required data element, such as patient name, within a prescription record. Error messages indicate the data was not loaded into the registry. A prescription record containing an error must be corrected and resubmitted to the MPDR by close of the next business day. During audit work, rule required submissions and corrections within eight days.

**Warnings Indicate Data Review:** A warning indicates incorrect data was submitted in a field not required in ASAP 4.1, such as an indicator for partial fill of a prescription. A prescription that contains a warning is still loaded into MPDR. The warning recommends correction by the submitter, but does not stop data from being submitted to the registry permanently because the submitted data is not considered a requirement for ASAP 4.1 standards.

### **Data Control Enforcement Should Be Conducted Regularly by the Board**

While these controls are in place, it is still up to a pharmacy to correct data errors. There is always the potential that pharmacies may not correct and resubmit prescriptions that were rejected by or had warning messages from MPDR. When this happens, data is missing from the registry and it reduces the reliability of information within the registry. The board has established procedures to hold the pharmacist in charge or pharmacy license-holder accountable through letters and phone calls for being out of compliance with reporting requirements.

Compliance Audit Reports (CAR) produced by MPDR are intended to help the board audit pharmacy compliance by identifying pharmacies that have not registered or submitted data. CARs also identify those pharmacies that have not addressed rejections, errors, and warnings. CARs are the board's only means to review and audit the accuracy of data maintained within the registry. These reports are part of MPDR's incomplete functionality and are not functioning as needed by the board. So, although these reports are available to the board, the reports are not reviewed on a regular basis nor can they be relied on.

### **Board Can Improve MPDR Data Integrity**

The board places significant reliance on CARs to review and audit MPDR data. Because they are not functioning correctly within MPDR, the board cannot provide complete assurance over the accuracy and completeness of the data. The current systematic controls and CARs do not identify data that is nonsensical or identify if pharmacies are entering information as required by rule; the controls only compare the data to the ASAP 4.1 format. Administrative Rules require additional data elements not included in ASAP 4.1 format. The format used is still accepted as a national standard, however it is not the most current standard available. We also found the board was not conducting regular reviews of pharmacy-reported errors and warnings. During our audit work, we noted the board had not reviewed the errors and warnings for 14 months. Delays like these in reviewing information do not hold pharmacies accountable nor ensure the integrity of MPDR data.

IT industry standards refer to creating, defining, and implementing procedures to ensure the integrity and consistency of all information in databases. Organizations need to consider the trustworthiness of data regarding data accuracy and integrity. Without this review, there is a risk that data the prescribers are using to verify their patients' prescriptions are unreliable.

We analyzed two years (2016 and 2017) of prescription data to identify the impact and extent of not reviewing data for completeness and accuracy. To test completeness, we compared data to reporting requirements established by rule and best practice. To verify accuracy of the data, we developed several data calculations and then reviewed the fields any reasonable person would question. Our review of MPDR data identified records that were permanently submitted with either incomplete or invalid data. The results of this review are discussed in the following sections:

**Patient Date of Birth:** We reviewed MPDR data for birthdates that appeared unreasonable. We identified several instances where birthdates within the registry were incorrect. For example, our review found people born prior to 1900, and people born after the date MPDR received the data.

We identified over 1,000 dispensing records that had a questionable patient date of birth in MPDR. These included:

- ♦ Four records had dates listed after we received the data (for example, 01/01/2020).
- ♦ 231 invalid dates (01/01/0001).
- ♦ 50 unlikely birthdates which occurred prior to 01/01/1900.
- ♦ Remaining records contained birthdates prior to 1912.

The accuracy of date of birth in MPDR is important because it is used to help identify patients along with first and last name. If the date of birth is wrong, a patient could be duplicated in the database or unidentified through patient searches.

**Prescription Dates and Refills:** Section 50-32-208, MCA, outlines prescription filling and refilling requirements for prescribing controlled substances. Our audit analyzed data within MPDR to determine if prescriptions were filled according to these requirements outlined in statute. We developed several date calculations and our analysis of the results found potential statute violations. These tests identified several issues concerning prescriptions written by prescribers and prescriptions refilled by pharmacies. Figure 3 (see page 30) provides specific results of these tests outlined below:

**Emergency Prescriptions:** The date the prescription was written was compared to the date it was filled to identify how long the prescription was being used and if the date filled was after the date it was written. In most cases this indicates an emergency prescription, allowed by law, that must be promptly reduced to writing. In total, we identified 147 of these instances. Further review of how many days were between the date filled and date written showed that half of these would not be considered “promptly” reduced to writing. Thirty-four of the prescriptions were written over 100 days past the date they were filled.

**Aged Prescriptions:** The age of a prescription was tested by calculating the time between the dates written and filled. This identifies how long ago a prescription was written and is still being used. Prescriptions should not be used for more than one year without being renewed by a prescriber, so we looked for prescriptions written prior to January 1, 2015. We identified 145 prescriptions being filled 1 to 2 years after they were written, and another 59 prescription fills ranging from 2 to 116 years after they were written. Further comparison to patient information indicate that the date written field made more sense as a birthdate.

**Refills:** Refill guidelines vary by the schedule of the drug. Schedule II drugs that are more addictive are not allowed to be refilled without renewal or review by the prescriber. Schedule III and IV drugs, which are moderately addictive, should not be refilled more than five times or after 6 months. While a refill number is required to be reported by all pharmacies, we had to create tests to count the number of times a prescription was refilled. This is because the refill number, while still a number in the registry, was not always accurate. Some prescriptions listed the first fill as refill 1 and some started at 0. This is an example of why it is important to verify sensical data, not just format. We identified over 20,000 Schedule II prescriptions that were issued refills, and almost 2,000 Schedule III-IV drugs with greater than 5 refills.

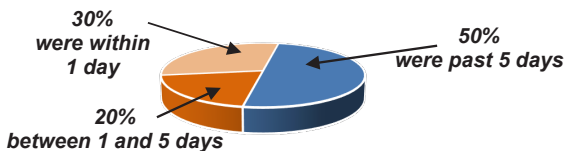
**Schedule III-IV Aged Prescriptions:** As noted above, Schedule III and IV drug prescriptions expire after six months and should not be filled after that. We compared the dates these prescriptions were written to the dates that were filled and found 362 Schedule III-IV prescriptions that were refilled after 6-month expiration.

Figure 3  
**Potential Issues Related to Prescription Dates and Refills**

**Emergency Prescriptions:** If controlled substances are dispensed without formal prescription, they must be promptly reduced to writing.



147 Prescriptions filled prior to being written



**Aged Prescriptions:** Prescriptions generally should not be filled a year after being written. For our data scope, this would be prior to January 1, 2015.



200+ Prescription Fills or Refills over 1 year old



Some dates appear to be patient birthdates

**Schedule II Refills:** Pharmacies are not allowed to refill these drugs unless filled partially or the prescription is renewed by a prescriber.



20,053 Prescriptions were refilled

7,643 Patient IDs received the prescriptions



295 Pharmacy IDs refilled the prescriptions

**Schedule III-IV Refills:** Schedule III-IV prescriptions are not allowed to have more than 5 refills unless renewed by a prescriber.



1,894 Prescriptions with more than 5 refills



196 Pharmacy IDs refilled prescriptions to 1,211 patient IDs

**Schedule III-IV Aged Prescriptions:** Schedule III-IV prescriptions are not allowed to be refilled after 6 months unless renewed by a prescriber.



362 Prescription Fills or Refills after 6 months

282 Patient IDs received prescriptions from 86 Pharmacy IDs



Source: Compiled by the Legislative Audit Division through MPDR data analysis.

The board does not conduct reviews or validations of incoming prescription data. It is unclear if our analysis results indicate suspicious prescription drug activity, if it is data entry errors, or a combination of both. In either case, this type of analysis shows the



board should conduct analytical testing and reviews so it can follow up on questionable data with submitting pharmacies. This would help improve MPDR data and help the board identify and investigate suspicious activity related to prescribing and dispensing prescription drugs. Investigations can result in a referral to Department of Justice (DOJ) and/or disciplinary action against a pharmacy.

## **Further Data Validations and Review Are Needed to Increase MPDR Usability**

We identified more than 23,000 questionable records within MPDR related to birthdates and prescriptions filled by pharmacies. This is a small percentage of the millions of prescription-related data in the registry. Regardless, these situations could be potential illegal dispensing of prescription medications and should have been investigated by the board.

We discussed these issues with the board and they indicated they place reliance on pharmacies to submit correct and timely data. For instance, the board claims the pharmacy systems prevent refills of Schedule II drugs. Partial fill of these drugs occurs often, which would create a situation where the prescription is in the registry multiple times with different fill dates. When this occurs, the pharmacy should be using the partial fill indicator within the registry; otherwise, these would appear to be complete refills. Further review of our results showed instances where the partial fill indicator in the system was not checked, indicating the patient received the full prescription each fill. However, there is blank data in the partial fill indicator for many prescriptions because pharmacies are not required to provide this information. So, this field is unreliable in determining if these are data entry errors or evidence of criminal activity. The board acknowledged MPDR does not contain an accurate reflection of partial and complete dispensing of a prescription. Since the board neither reviews this data nor discusses these issues with pharmacies, the extent and actual cause for these data patterns observed in our analysis are unknown.

The board needs to improve data quality assurance procedures to ensure the integrity of MPDR data. While the board cannot change data, they can develop stronger validations for data entry within the system. Options for addressing additional fields including date written, date of birth, and date filled include:

- ◆ Validating data within the registry at data submission and through compliance reviews so nonsensical data can be identified.
- ◆ Using date and refill validations to determine if pharmacies are reporting incorrect information or are in noncompliance with state law.

---

**RECOMMENDATION #5**

*We recommend the Department of Labor and Industry work with the Board of Pharmacy to implement formal procedures to ensure validation and quality assurance of Montana Prescription Drug Registry data.*

---

## **Inconsistent and Out-of-Date Reporting Requirements**

The board follows the ASAP 4.1 reporting standards. Pharmacies use these standards nationwide for various sorts of reporting, including prescription drug monitoring reporting. ASAP standards are used by every state with a prescription-monitoring program. However, current standards are now at version 4.2a, which includes additional reporting capabilities and data refinement. For example, they include treatment type and further clarification on quantity dispensed and prescribed, which helps identify what is reported in the partial fill indicator field. These additional data fields and capabilities would allow the DLI to refine misuse and diversion analysis as well as be able to further rely on the data to improve patient safety.

Administrative Rule also requires data elements be reported in MPDR in addition to the ASAP requirements. These include:

- ♦ Pharmacy contact information
- ♦ Patient gender information
- ♦ Prescriber contact information

## **Missing Data Fields Diminish the Usability and Effectiveness of MPDR**

Due to the importance of following national reporting standards and having consistent data reporting requirements, we compared the fields required by national standards and administrative rule. This comparison was done to identify what data was being populated and reported in MPDR. This provides an understanding of how complete MPDR data are and how reliable the system is for prescribers, pharmacies, and the board.

We found 334,000 records of a total 3.9 million (9 percent) were missing at least eight administrative rule-required data fields. One primary field missing was complete pharmacy contact information. Pharmacies do not have a unique ID by location and only report owner name. For example, if Pharmacy A changed owners, it would

become Pharmacy B and be assigned a new ID. If pharmacy addresses were required, a potential investigation would be able to identify patients that are attempting to get the same prescription filled at several pharmacies, a practice known as pharmacy shopping. Addresses would be able to capture how many different pharmacy locations a patient visited.

We also identified 437,000 dispensing records (11 percent) missing a gender code as required by ASAP 4.2a. Missing gender codes limits the board's ability to identify duplicate patients. Identifying duplicate patients allows prescribers to conduct more reliable searches as well as to further address suspicious activity.

## **Board Needs to Update Reporting Requirements**

In 2013, Senate Joint Resolution Study 20 was approved to study ways to reduce prescription drug abuse. Within that study, several recommendations were made to improve MPDR and to address prescription drug abuse in Montana. One of the recommendations was to improve shared data by aligning with ASAP 4.2 standards. According to the board, it wanted to focus on getting the basic functionality implemented for stakeholders, so updating the system to align with national standards was not a priority. ASAP 4.1 continues to be a valid national standard still followed by some states.

Using the most recent ASAP standards allow the board to gather necessary information to make the registry more effective, reliable, and useful for the medical community. Additional information required by administrative rule provides further assistance in identifying unique patients, prescribers, and pharmacies. The ability to identify unique individuals is crucial when trying to keep complete records of patient prescription history. Using updated reporting requirements also allows the board to better communicate with other states and provide more data, thereby increasing protection for patients. Once consistent and correct data is gathered, the foundation is established to better analyze data for addressing misuse and diversion. This also provides the board the ability to educate pharmacies on submitting data and dispensing laws.

---

### **RECOMMENDATION #6**

*We recommend the Department of Labor and Industry and the Board of Pharmacy follow administrative rule by requiring all data elements in pharmacy reporting be included in the Montana Prescription Drug Registry.*

---



## Chapter V – Activities to Identify Misuse and Diversion of Prescription Drugs

### Introduction

The Board of Pharmacy (board) does not currently conduct reviews and analysis of reported data to alert pharmacies or prescribers of potential issues. Instead, it relies on medical professionals to make their own conclusions about a patient's prescription history when reviewing Montana Prescription Drug Registry (MPDR) data. Not providing evidence of misuse and diversion, the intentional transfer of a controlled substance to use other as directed, puts patients at risk and increases the potential for prescription drug abuse. Misuse of prescription drugs is defined as using the drug for purposes other than what it was prescribed for. By proactively identifying and addressing misuse and diversion, issues can more readily be resolved before they become a public health concern. We found potential cases where prescription drugs were dispensed inappropriately, such as filling prescriptions past approved refill dates and prescriptions filled by multiple pharmacies.

By not identifying misuse and diversion, the board is at a disadvantage for receiving federal grant funding. Best practices indicate agencies will be given priority consideration for grant funding if they are proactively addressing misuse and diversion. For example, according to the US Department of Justice, the Montana Board of Crime Control (MBCC) was denied federal grant funding in 2018 because the application did not include specific information about how the registry could enhance the state's capacity to respond to the substance abuse crisis. Based on previous years' awarded amounts, the board could have been awarded up to \$400,000 in federal grant funding from MBCC.

Our fourth audit objective was to determine if MPDR data can effectively identify misuse and diversion. Misuse and diversion has several definitions and can include many different activities in healthcare. Some states describe it as fraudulent activity, whereas some states identify it as questionable or suspicious activity. This chapter discusses our work and recommendation related to this area.

### Criteria to Identify Misuse and Diversion of Prescription Drugs

Section 37-7-1502, MCA, does not provide a specific definition for misuse and diversion; however, administrative rule states it can be defined as patients visiting four or more prescribers in a 60-day period or four or more pharmacies in a 60-day period. This activity is more popularly known as doctor shopping. Best practices that

we reviewed from other states set the time frame for doctor shopping at 30 days and include criteria for activities other than doctor shopping, like prescriber activity. Other states also identify other criteria for defining misuse and diversion, including suspicious prescribing activity. Montana has data sharing agreements to report prescription drug activity between neighboring states. Our tests used both the criteria in rule and best practice from other states.

During our audit work, we conducted multiple tests using MPDR data which are described in the following sections. We used caution in conducting our test knowing some MPDR data is unreliable. We also acknowledge that some decisions are valid based on doctor-patient relationships. However, we believe there is sufficient data in the registry to determine if there appeared to be potential instances of misuse and diversion occurring.

### **Issues With Unique IDs Were Identified**

Prior to testing for questionable activity, we needed to review whether ID numbers for patients, prescribers, and pharmacies were unique. Otherwise, a patient with multiple ID numbers going to multiple pharmacies might not be observable because it would look like different patients each time. The same would happen if prescribers did not have unique ID numbers as well.

To test these IDs for uniqueness, we reviewed the database tables with information specific to that ID in it, not the dispensing history. For instance, the table with pharmacy information in it has a pharmacy ID along with pharmacy name, address, and contact information. Because the table is specific to pharmacy information, there is no dispensing information in it. By testing these database tables for duplicate records, we identified three types of ID numbers that are not unique. These are discussed below.

**Patient ID Numbers:** To verify the uniqueness of patient IDs, we pulled a sample of patients and ran tests that identified patient records appearing to be similar. Our sample of 9,211 patients found 738 potential duplicates. We manually reviewed each of these records to verify if duplicate patients existed by comparing first and last name, date of birth, and address. We were able to clearly identify 215 duplicate patient IDs.

Patient ID numbers were not unique for several reasons. One is related to MPDR functionality being developed by the contracted vendor without input from the board. This issue was discussed earlier in the report. Several data entry errors were also identified due to misspelling names or entering incorrect or inconsistent patient birth dates. This resulted in several patients in the registry having multiple ID numbers instead of a number unique to them for all prescriptions they are issued.

**Prescriber ID Numbers:** All prescribers and prescribing facilities are issued a unique ID number by the Drug Enforcement Administration (DEA). Prescribers have the option to provide either their associated facility's DEA number or their own personal DEA number. We found this resulted in inconsistent data within MPDR that impacts the ability to count the number of prescribers for whom a patient has received prescriptions. When counting the number of different providers tied to a DEA number, we identified multiple instances where a facility DEA number was used for the prescriber ID. Due to this, we used a combination of prescriber fields to identify prescribers in our testing. This would ensure we did not miss potential doctor shopping if a patient visited multiple doctors using the same DEA number.

**Pharmacy ID Numbers:** While reviewing prescription filling practices for data reliability, we identified instances where pharmacy addresses were the same for multiple pharmacy IDs. This indicates pharmacies do not have unique ID numbers either. Because the pharmacy address information is not required in reporting, this information is missing for some pharmacy ID numbers and we could not determine how many duplicate pharmacy ID numbers existed. When discussing this with the board, they explained that pharmacy ID numbers are tied to the owner of the pharmacy. If a pharmacy has a change in ownership the ID number changes for that location. This impacts the identification of the potential pharmacy shoppers or patients who use multiple pharmacies concurrently. It also increases the reliance on other pharmacy information that we determined to be incomplete in the registry.

### **Potential Evidence of Patient Misuse and Diversion**

Even though duplicate ID numbers exist in MPDR, our audit work was still able to identify suspicious patient activity, such as potential doctor shopping. Doctor shopping is when someone goes to multiple medical professionals to fill or refill unneeded prescriptions. Administrative rule indicates misuse and diversion as a patient receiving four or more prescriptions of the same type of drug, or filling prescriptions from four or more pharmacies, within a 60-day period. Due to the amount of data in prescription drug registries, best practices from other states indicate reducing that window to 30 days. Doing this can help limit results and focus on more egregious activity. To understand the difference in these two criteria specific to Montana, we conducted analysis for suspicious activity in both a 30-day time frame and 60-day time frame. To test this, we used MPDR data to determine if a patient received similar prescriptions from four or more prescribers and filled them at four or more pharmacies within the allotted time. To focus the results of our analysis, we ran these test on only highly addictive prescription drugs within Schedule II.

We ran tests that counted the number of subsequent prescriptions within the specified time frame for each prescription a patient received. We were then able to identify those greater than four and count the number of different prescribers and pharmacies that occurred within that time frame as well. Figure 4 (see page 39) provides an example of a situation we identified where potential doctor shopping might have occurred during the 2016-2017 time frame. Overall, we identified 4,410 patient IDs that went to four or more pharmacies and four or more prescribers in a 30-day period. We identified 8,814 patient IDs that visited four or more prescribers and pharmacies in a 60-day period. Figure 4 shows two examples identified in our analysis.

- ◆ Patient #1 received nine prescriptions for high strength opioids from four different prescribers within a 30-day period. These were filled at four different pharmacies. When expanded to 60 days, two more prescribers were visited for the same type of high strength opioids.
- ◆ Patient #2 received 11 prescriptions from 9 different prescribers within a 30-day period. These were filled at 5 different pharmacy locations.



Figure 4  
**Suspicious Patient Activity Analysis**

### Doctor Shopping

4 or more prescribers and  
4 or more pharmacies

*Within  
30 Days*

**4,410**  
*Patient IDs*



*Within  
60 Days*

**8,814**  
*Patient IDs*

Patient #1							
Doctor #	Date Written	Drug Name	Days Supply	Partial/ Full	Date Filled	Pharmacy #	Pharmacy City
1	4/4/17	Hydrocodone-Acetaminophen	2	Full	4/4/17	1	Kalispell
1	4/10/17	Hydrocodone-Acetaminophen	2	Full	4/10/17	1	Kalispell
2	4/12/17	Hydrocodone-Acetaminophen	28	Full	4/12/17	2	Helena
3	4/24/17	OxyCONTIN	5	Full	4/24/17	3	Spokane
3	4/24/17	OxyCODONE HCl	1	Full	4/24/17	3	Spokane
4	4/24/17	OxyCONTIN	7	Full	4/25/17	3	Spokane
4	4/26/17	OxyCODONE HCl	8	Full	4/26/17	4	Whitefish
4	4/28/17	OxyCONTIN	10	Full	4/28/17	3	Spokane
4	5/1/17	OxyCONTIN	6	Full	5/1/17	3	Spokane
Patient #2							
Doctor #	Date Written	Drug Name	Days Supply	Partial/ Full	Date Filled	Pharmacy #	Pharmacy City
1	12/6/16	Hydrocodone-Acetaminophen	2	Blank	12/6/16	1	Bozeman
2	12/7/16	Oxycodone-Acetaminophen	2	Blank	12/7/16	1	Bozeman
3	12/9/16	Oxycodone-Acetaminophen	2	Blank	12/9/16	1	Bozeman
4	12/10/16	Hydrocodone-Acetaminophen	1	Blank	12/10/16	2	Dillon
5	12/12/16	OxyCODONE HCl	10	Full	12/12/16	3	Sheridan
6	12/19/16	OxyCODONE HCl	1	Full	12/19/16	4	Dillon
7	12/20/16	OxyCODONE HCl	1	Full	12/20/16	5	Missoula
8	12/22/16	OxyCODONE HCl	7	Full	12/22/16	4	Dillon
9	12/26/16	OxyCODONE HCl	3	Full	12/27/16	4	Dillon
8	12/29/16	Hydrocodone-Acetaminophen	5	Full	12/29/16	5	Dillon
5	1/3/17	OxyCODONE HCl	8	Blank	1/3/17	1	Bozeman

**Source: Compiled by Legislative Audit Division from Montana Prescription Drug Registry data.**

As noted in the figure, this example shows both patients obtaining prescriptions from different locations across Montana and in neighboring states within 30 days. In addition, Patient #1 also received two prescriptions for OxyContin, a high-strength pain medication, on the same day from two different prescribers. There may be reasonable explanations why situations like those described in the figure may occur. However, with the number of prescribers seen and pharmacies located across Montana and in neighboring states, it could be an indication of potential patient misuse and diversion of prescribed medications.

Additionally, because Montana still allows paper prescriptions, we also tested for potential pharmacy shopping. Pharmacy shopping is the act of visiting multiple pharmacies in a short period of time with the same prescription from one prescriber. The expectation of the test was minimal considering the growth of electronic prescriptions being used. We identified six patient ID numbers that took a prescription to four different pharmacies within 60 days.

These potential instances of doctor and pharmacy shopping show that MPDR can provide evidence of suspicious activity that should be considered by prescribers and pharmacists prior to issuing prescriptions. The board is not currently reviewing MPDR data to identify suspicious activity. According to §37-7-1502, MCA, the board has the right to review and test MPDR data to identify potential misuse and diversion and possible criminal activity. However, statute is permissive and does not require analysis to occur. The board chooses not to be proactive by conducting these types of analyses.

### **Potential Prescriber Misuse and Diversion Can Also Be Identified Using MPDR Data**

Prescriber misuse and diversion is the highest risk to patient and community safety because prescribers control what a patient is given. If the patient is receiving more than the recommended amount, substance abuse and addiction increases significantly. We used several federal and state statutes as well as best practices and guidelines to prevent this kind of activity in our tests. These are described below.

**Active License Test:** According to §37-3-301, MCA, a prescriber is required to have a valid, active license to prescribe controlled substances or the prescriber faces misdemeanor charges. We tested whether prescribers were prescribing controlled substances without an active license by comparing active license information to prescriber data on dispensed records from November 2017.

There may be prescribers listed in the registry that do not have a listed license in the Montana licensing database due to nonresidents visiting Montana and needing refilled prescriptions. The nonresident's doctor would be listed, but would not have an active Montana license number. However, those types of prescribers would be limited and are not easy to identify in MPDR data because prescriber location information is not captured.

If rule reporting requirements were followed, we would have been able to identify out-of-state prescribers and remove them from this test. Instead, we reviewed the amount of dispensing records each provider had within the one month. If a prescriber was out-of-state, it would be reasonable for prescriptions to be filled when the prescriber was close to a state line or a patient was on vacation in Montana and needed a refill. We

found multiple prescribers with over 50 fills or refills of prescriptions in one month. Because we do not have prescriber location, we cannot verify these occurrences are valid exceptions.

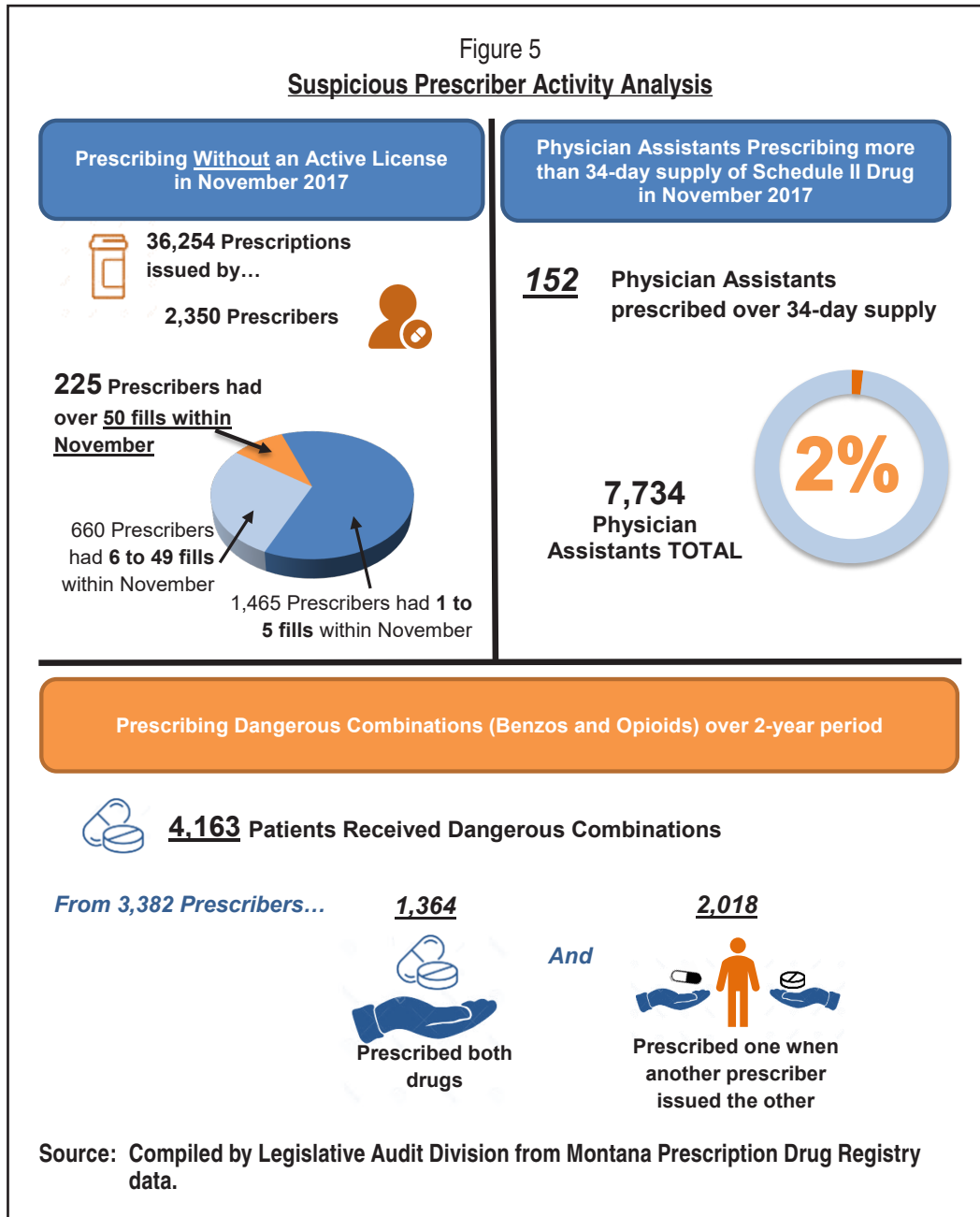
**Days of Supply Test:** According to §37-20-404, MCA, Schedule II substances are not to be prescribed by a physician assistant for more than a 34-day supply due to being highly addictive and dangerous. For prescribers that we could identify a license type for, we separated the physician assistants and reviewed the days of supply dispensed on the prescription record.

**Prescribing Dangerous Combinations Test:** Recent suspicious prescribing patterns include prescribers authorizing dangerous combinations of drugs. According to federal recommendations, high risk lies with prescribing benzodiazepines (benzos) and opioids concurrently. While this may still be an acceptable practice, patients prescribed both are more likely to become addicted to or die from an overdose even if taking them for a medically-appropriate reason or prescribed amount. Overlapping benzo and opioid prescriptions could be a sign of suspicious prescription drug use or suspicious prescribing practices.

We analyzed prescriptions for Schedule II drugs during 2016-2017 to see if a patient was prescribed a benzo while also taking an opioid, either by the same or different prescribers. Using the days of supply indicated on the record and the date it was filled, we calculated a date range for the prescription. We were then able to identify if any other prescriptions for benzos or opioids were prescribed during that date range. For example, if Prescriber #1 prescribed a benzo on January 1 with 21 days' supply, we would be able to identify if that patient received an opioid between January 1 and 22, indicating inappropriate prescribing activity. Through the testing we also identified instances where the patient received an opioid, but then the patient went to another prescriber to get a benzo. This example shows where MPDR can provide useful and valuable information to Prescriber #2 about other medications the patient is taking.

Testing MPDR data for the scenarios described above identified suspicious provider activity:

- ♦ Using licensing information from DLI's licensing database, we found over 2,000 prescribers who wrote prescriptions without an active license in November 2017.
- ♦ 152 physician assistants were in violation of §37-20-404, MCA, by prescribing Schedule II drugs for over a 34-day supply.
- ♦ Over 4,000 patients received dangerous combinations of drugs. Two-thirds of the prescribers involved were not the same prescriber that issued the initial drug.



## Suspicious Activity Needs to Be Defined and Reviewed to Improve Patient Safety

The board faces many challenges in addressing misuse and diversion of controlled substances. Many of the issues we identified, such as duplicate patients, are common nationally. However, we found other states are attempting to address misuse and diversion to improve patient safety through analysis of prescription data. Statute requires the board to collect prescription information and allows them to review the

data for misuse and diversion. The board can make improvements and implement mechanisms to help address suspicious prescription drug activity in Montana.

The results of our analysis may have many reasons for occurring, including bad data entry, medical staff not reviewing prescription data prior to prescribing, limited education and awareness of prescription rule and law, unclear or unestablished definitions of suspicious behavior, or actual patient/prescriber misuse and diversion. The ability to identify patterns and trends would help pinpoint problems so the board and other entities can start developing meaningful and effective ways of preventing misuse and diversion.

Because MPDR data is not reviewed, patient safety and public health is not completely protected. The board has the authority to review the data and identify issues to improve patient safety. Procedures need to be established to ensure it is not held accountable if a litigation situation were to occur.

---

#### **RECOMMENDATION #7**

*We recommend the Department of Labor and Industry work with the Board of Pharmacy to protect patient safety and public health by developing and implementing data analysis tools and procedures to identify and address potential misuse and diversion of prescription drugs using Montana Prescription Drug Registry data.*

---



## Chapter VI – Montana Prescription Drug Registry Direction and Resources

### **Introduction**

The Board of Pharmacy (board) is required by §37-7-1502, MCA, to manage and maintain the Montana Prescription Drug Registry (MPDR). However, as discussed in previous chapters we identified several ongoing management issues related to the maintenance of the registry since its inception. These issues include:

- ♦ Unestablished management procedures and responsibilities leading to contract weaknesses, project delays, unusable functionality, and limited ability of the board to implement new functionality required within the industry.
- ♦ Delayed completion of system functionality needed to comply with statute and rule.
- ♦ A lack of necessary procedures to help identify MPDR security weaknesses.
- ♦ Data integrity weaknesses impacting the usability and effectiveness of the registry.
- ♦ Minimal reviews of MPDR data that would identify potential inappropriate or illegal prescription drug activity to help improve patient safety.

While our previous recommendations discuss the need to establish various procedures, increase system functionality, and clarify staff responsibilities, there are primary causes consistent with the findings to be addressed: coordination between invested stakeholders, like Department of Justice (DOJ) and Department of Public Health and Human Services (DPHHS), and limited resources allocated within the board to effectively manage the registry. These foundational changes need to be addressed for the Department of Labor and Industry (DLI) and the board to effectively maintain a reliable prescription drug registry.

### **Coordination of Resources Is Needed to Support Management of MPDR**

MPDR is currently managed by one full-time DLI staff (funded by the board) and the board's executive officer who oversees the staff member. The administrative staff member is required to manage all aspects of the registry. This includes managing the MPDR vendor contract, monitoring MPDR system development, overseeing security of personal health information (PHI), managing system maintenance, providing customer support, managing MPDR users, and ensuring accuracy, integrity, and security of prescription data. Throughout our audit, we found many of these duties

were not prioritized due to completing other important tasks required to keep the registry up and running. These other tasks included:

- ♦ Budget monitoring and planning for future enhancements and changes to MPDR.
- ♦ Updating documentation to ensure MPDR procedures and guidelines are current and defined.
- ♦ Researching and documenting workarounds for partial functionality so users can complete necessary tasks within the registry.
- ♦ Maintaining professional development to ensure MPDR is in alignment with other states to help Montana keep current with national prescription drug monitoring best practices.
- ♦ Web updates allowing users and stakeholders a centralized location for MPDR information and a portal for registry access.
- ♦ Conducting compliance audits that serve as the board's only audit tool for ensuring pharmacies are reporting prescription data.
- ♦ Developing a request for proposal (RFP) to implement a new prescription drug registry.

Based on information systems best practices and industry standards, several positions should be charged with contract and project management of information systems. In addition, dedicated security specialists and trained technical support staff are also required. These duties are typically performed by separate individuals trained specifically in these areas to ensure effectiveness and compliance with policy, law, and national information technology (IT) standards. However, these responsibilities for managing MPDR are all placed within one DLI position description and staff member. We found the DLI staff member has limited training in several areas including security of PHI, contract management, and IT project management. The position description also does not require knowledge or experience in these specific areas, but only a knowledge of the principles and practices of information systems. We also found the staff's position description assigns the position to a DLI unit that no longer exists. Based on this, we believe neither the board nor department have reviewed or considered what skills or resources are necessary to ensure MPDR is properly managed.

When reviewing other state agencies with systems similar to the registry, we found most have several full-time staff allocated to system management and administration. This includes contract management, project management, security, and operation support such as technical assistance. While structures for how agencies decide to use staff may vary, our work represents examples of how multiple full-time staff are needed to effectively manage IT systems. Most often, we found contract and security



management resources are shared among various systems within an agency. Some examples are provided below:

- ♦ DLI has a specialized security officer within its Technical Services Division (TSD) to assist other divisions with system security management.
- ♦ Security of tax data is managed by an office of three full-time staff within Department of Revenue.
- ♦ DPHHS has four full-time staff dedicated to information security for the department and five full-time staff dedicated to and specialized in project management.
- ♦ Most agencies have multiple, dedicated contract management officers.

After discussing management findings with the DLI, TSD assigned a project manager to assist with future project development.

## **Limited Resources Impacted MPDR Planning and Management**

The DOJ initially brought forward HB83 during the 2011 Legislative Session to create the registry, but registry oversight was assigned to the board instead of instead of DOJ. To help with MPDR implementation, the board received input from stakeholders. However, due to decisions by the board and DLI to move forward with core functionality requested by users, the registry was launched without all authorized functions in place. These initial decisions created resource limitations for MPDR and delayed adding new enhancements to the registry. The board and DLI have begun coordinating resources to address these issues.

Board officials also believe a new system could improve, reduce, or eliminate issues that currently exist with MPDR. While this may reduce time spent on system maintenance and manual work, it is unlikely to address weaknesses currently being experienced with MPDR. This is because expertise in specific areas, such as MPDR security, contract management, oversight of project implementation, etc. is required to properly manage MPDR, whether it develops a new system or continues to make improvements to the existing registry. The board and DLI need to analyze how to best leverage department resources to ensure MPDR is implemented and managed appropriately. This includes areas such as security, project implementation, and contract management. They also need to formally analyze what resources are needed to ensure the effectiveness, security, and cost-efficiency of the system, including if it already has resources available that could be redirected to meet MPDR management needs. This analysis should also be considered as part of the ongoing RFP development for a new prescription drug registry. An RFP should not be issued until a formal resource needs assessment is completed and the department and board know what resources are needed to properly manage the registry.

---

**RECOMMENDATION #8**

*We recommend the Department of Labor and Industry and the Board of Pharmacy:*

- A. Conduct a formal analysis to determine the resources needed to properly manage the Montana Prescription Drug Registry.*
  - B. Complete this analysis before a request-for-proposal for a new prescription drug registry is issued.*
- 

### **Advisory Group Established to Help Direct MPDR Operations**

During the 2011 Legislative Session, a prescription drug advisory group was created as part of the legislation creating the Montana Prescription Drug Registry. Section 37-7-1510, MCA, requires the board to establish an advisory group to provide information and advice regarding registry development and operation. This includes, but is not limited to:

- ◆ Criteria for reporting information from MPDR to pharmacists and prescribers.
- ◆ Design and implementation of registry educational courses.
- ◆ Standards for evaluating registry effectiveness.
- ◆ Administrative rules for establishing and maintaining the registry.

This law also requires the advisory group to be comprised of a variety of representatives including:

- ◆ Health care licensing boards that oversee healthcare providers who have the authority to prescribe or dispense drugs.
- ◆ Associations that represent healthcare professionals who have authority to dispense or prescribe drugs.
- ◆ Associations that advocate for patients.
- ◆ Entities involved in tribal health services or issues.
- ◆ The Department of Justice.

Section, 37-7-1510, MCA, also allows the advisory group to identify other individuals to be appointed to the group. The law places responsibility for establishing rules for conducting advisory group business on the board. Administrative Rule 24.174.1711

states the group shall establish policies and procedures to carry out duties as well as meet at least annually.

We found other states also use advisory groups, boards, or councils to help manage and make decisions on the effectiveness and progress of their respective prescription drug registries. States with advisory boards have representatives from health care organizations, law enforcement, and representatives from the legislature. These advisory committees serve several purposes including providing guidelines and advice on operations and management over prescription drug programs. Other tasks include analyzing progress made toward reducing prescription drug abuse, development of strategic plans, and developing criteria for reviewing data, and reporting matters for further investigations.

### **More Direction on the Management of MPDR Is Needed From Advisory Group**

According to the DLI, the advisory group was formed at initial development to ensure user business needs were met. The group met sporadically from 2011 to 2016 while the system was being developed, after implementation, and through major system changes. During our audit work, we determined the advisory board had not met since 2016 because new enhancements to the registry had not been made. This meeting was limited to providing the group with high level updates on MPDR statistics, an overview of recent implemented functionality, administrative rule changes, updated policy and procedure documentation, and general program updates. According to board officials, they are still working on initial suggested changes and decisions made by the advisory group. Based on our work, we do not believe the advisory group has established ongoing evaluation of the effectiveness of the registry.

The prescription drug registry advisory group has not actively met to discuss registry deficiencies, registry concerns among stakeholders, operational issues, and strategic plans on how to better address patient safety. The board has not developed the rules to require and enforce consistent group meetings, which resulted in a lack of direction to effectively maintain a registry that is up-to-speed with industry standards and trends. These advisory group meetings are needed to establish ongoing direction and improvement, which also includes consideration, prioritization, and implementation of stakeholder recommendations.

## **Senate Joint Resolution 20 Recommended Registry Enhancements**

Senate Joint Resolution 20 (SJR 20) was passed by the 2013 Legislature and authorized a study to address ways to reduce prescription drug abuse. The Legislative Council assigned the study to the Children and Families Committee and was mandated in part to review registry funding and functionality. The study was completed in 2014 and provided a list of proposed enhancements to the registry. The SJR study recommended the following features be added to the registry:

- ◆ Enter comments on patients.
- ◆ Integrate medical marijuana information.
- ◆ Allow unsolicited reporting for several patients.
- ◆ Allow scheduled queries on patient information and prescription data.
- ◆ Require real time/daily reporting.
- ◆ Linking electronic health records and profiles with MPDR.
- ◆ Additional reporting requirements/options.

The study also estimated an additional \$390,000 was needed above the original \$500,000 that was authorized to implement this additional functionality and maintain the registry through 2015.

During our audit work, two recommendations from the SJR 20 study were implemented through an administrative rule change and the enactment of Chapter 130 of the 2019 Legislative Session. Changes made related to improving prescription drug reporting and linking to electronic health patient profiles used by medical professionals. Administrative Rule 24.174.1704 recently changed the MPDR reporting requirements from eight days to one day. Section 37-7-1506, MCA, was modified to establish the requirement for linking electronic medical records with prescription drug history.

Following the SJR 20 study and its recommendations to improve MPDR functionality, the prescription drug registry advisory group instead had to focus on improving existing functionality to get the basic business needs implemented for front end users, such as doctors and pharmacies, because they were not yet fully operational. As a result, the recommended functionalities from the SJR 20 study were not prioritized or implemented. According to board officials, some of the proposed functionality is not feasible. The prescription drug advisory group has not provided the board guidance on implementation of feasible MPDR functions, if a new prescription drug registry is necessary, or potential resource needs to effectively manage the registry.

## **Prescription Drug Registry Advisory Group Could Provide Ongoing Guidance on the Registry**

We believe that without input and direction from the prescription drug registry advisory group, MPDR has not been properly managed. Had the advisory group established policies and procedures defining the role of the group, it could have served as a resource to the board in management, oversight, and future direction of the registry. We identified several areas where the advisory group could have been a resource to the board. Examples include:

- ♦ The board is developing an RFP for a new prescription drug registry. The advisory group could provide guidance on development of a new system to ensure all stakeholder needs are met and a new system runs as effectively as possible.
- ♦ Providing input on best practices on how the registry can best serve the state and the public and guidance/expectations related to security governance, contract management, project management, and ensuring the intent of the registry is met.
- ♦ As prescription drug abuse tactics change, the advisory group could review current operations of the registry to determine where enhancements and changes might be needed to address changing risks.
- ♦ There are multiple resources already available within DLI to address constraints. The group can advise ways to meet the needs of the registry now and plan for the resource needs of the registry in the future.

The prescription drug registry advisory group includes a variety of stakeholders with an interest in ensuring proper oversight of prescription drugs. Because of this, its involvement in development and operation is critical. However, advisory group involvement has been sporadic at best, and it has not met in three years. The board has not actively sought to engage the prescription drug registry advisory group to assist with MPDR oversight.

We found other states have actively engaged prescription drug advisory groups to help provide guidance to pharmacy boards regarding their drug registries. For example, Oregon uses an advisory commission and they meet quarterly to discuss developing criteria for evaluating prescription drug data and making recommendations to health authorities regarding the operation of the program. We believe Montana's prescription drug advisory group could aid the board regarding MPDR operations and development. We also believe the advisory group would benefit defining prescription drug misuse and diversion. Currently, prescription drug misuse and diversion are not clearly defined in either law or rule. The only definition is found in Administrative

Rule 24.174.1706 stating the following factors are “suggestive” but not conclusive evidence of misuse or diversion:

- ♦ Four or more prescribers in a 60-day period, or
- ♦ Four or more pharmacies in a 60-day period

One main purpose of MPDR is to identify misuse and diversion of prescription drugs and a lack of clarity on what misuse and diversion is limits the usefulness of the registry and can impact patient safety. Similar to how Oregon’s commission provides guidance and defines misuse and diversion, more specific definitions regarding misuse and diversion are needed to increase patient safety and registry effectiveness. Montana’s prescription drug registry advisory group should be providing similar guidance and defining what specifically constitutes misuse and diversion.

### **Prescription Drug Registry Advisory Group Requires More Frequent Meetings, Inclusive Membership, and Transparency**

It is important the board get the prescription drug advisory group involved in registry oversight to receive proper guidance on the registry. This includes ensuring membership includes all possible stakeholders, establishing regular ongoing meetings, and establishing a clear vision of what the board needs from the advisory group. State law allows stakeholders other than those specifically listed to be part of the prescription drug advisory group. The board should look at expanding the advisory group to include other stakeholders who could have input regarding MPDR and how it best serves the public need. Administrative Rule 24.174.1711 includes legislators as part of advisory group membership and this provides an important public policy perspective. However, examples of other membership could include local law enforcement or members of the public.

Administrative rule requires the Prescription Drug Registry Advisory Group to develop policies and procedures necessary for them to carry out their duties. However, the board has also not engaged the group to develop policies and procedures. This has resulted in few meetings occurring between the advisory group and the board. More involvement and interactions between the board and the advisory group would help alleviate the weaknesses we identified related to MPDR, including a lack of a clear definition regarding misuse and diversion of prescription drugs. Finally, increasing activities and interactions between the board and the advisory group also increases the necessity of transparency regarding the business they are conducting and decisions being made regarding MPDR activities. By increasing group activity, discussions regarding the resources allocated to the registry can occur, including assessments of

whether the registry should be housed within the board. This would also allow them to provide additional information in current usage reporting such as MPDR activities, changes, and prescription drug use in Montana.

---

**RECOMMENDATION #9**

*We recommend the Board of Pharmacy work with the Prescription Drug Advisory Group to:*

- A. Establish formal policies and procedures regarding business processes that include regular, ongoing meetings.*
  - B. Expand advisory group membership to include other stakeholders important to prescription drug evaluations and discussions.*
  - C. Revise and update administrative rule to better define potential misuse and diversion thresholds to improve patient safety.*
-

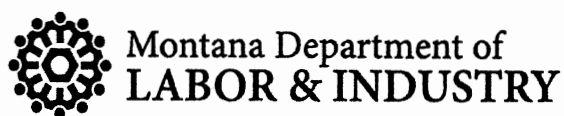




DEPARTMENT OF LABOR  
AND INDUSTRY

DEPARTMENT RESPONSE





May 31, 2019

Angus Maciver  
Legislative Auditor  
Legislative Audit Division  
PO Box 201705  
Helena, MT 59620-1705

RECEIVED

JUN 04 2019

LEGISLATIVE AUDIT DIV.

**Subject: Information Systems Audit #18DP-01 of the Montana Prescription Drug Registry; Montana Board of Pharmacy and Montana Department of Labor and Industry**

Dear Mr. Maciver:

The Department of Labor and Industry has reviewed the 2019 Report of the Information Systems Audit conducted regarding the Montana Prescription Drug Registry (MPDR). The Department would like to thank your audit staff for their review. As a Department we are always looking for ways to improve and we appreciate the efforts of others to help assure we are providing quality services with the best accountability possible. Our responses to the audit recommendations appear below.

***Recommendation #1***

**We recommend the Department of Labor and Industry regularly coordinate with the Board of Pharmacy to establish, follow, and enforce project and contract management procedures to include:**

- A. Definitions for communication expectations and responsibilities,**
- B. Management of project changes and enhancements, and**
- C. Adherence to state procurement standards.**

**Response:** The Department concurs with the recommendation. The Department agrees that adherence to standard procedures and best practices for IT system contract management required improvement during the first years of the MPDR timeline. LAD correctly notes the Department is now following standard procurement processes and procedures and is leveraging Department and State resources to do so. More specifically, beginning in 2015 through the present, multiple changes have been made to improve procurement and project management and oversight:

1. Department and vendor representatives, as well as program staff now meet monthly to discuss timelines, contract issues, and next steps.



2. The Business Standards Division (BSD) assigned a Business Systems Analyst to assist with MPDR project management and any necessary coordination with the Department's Technology Services Division (TSD) in August 2015.
3. TSD assigned an IT project manager to the MPDR project/system in July 2015.
4. Future projects will use documents which adhere to and enforce state procurement standards and best practices. 2017-2019 Department of Administration Delegation Agreement.
5. MPDR project management and contract performance are a standing agenda item on monthly Business Standards Division (BSD)/TSD planning and operations meetings.

### ***Recommendation #2***

**We recommend the Department of Labor and Industry and the Board of Pharmacy:**

- A. **Work with Department of Public Health and Human Services to immediately and permanently destroy or deidentify prescription drug data older than three years.**
- B. **Develop a data destruction and retention plan to ensure destruction of shared prescription drug data.**

**Response:** The Department concurs with the recommendation. The Department of Public Health and Human Services (DPHHS) confirmed in March of 2019 that it deleted all individually identifiable MPDR data in October of 2018. In addition, the data transfer memorandum of understanding (MOU) with DPHHS is being amended to specifically direct the timeline for destruction of the identifiable data older than 3 years for subsequent transfers of MPDR data. The Department will finalize the amended MOU by June 2019.

### ***Recommendation #3***

**We recommend the Department of Labor and Industry work with the Board of Pharmacy to develop a governance structure and implement a security plan for the Montana Prescription Drug registry that:**

- A. **Defines the security responsibilities,**
- B. **Requires annual risk assessments,**
- C. **Mitigates significant security risks as identified, and**
- D. **Ensures compliance with HIPAA security rules.**

**Response:** The Department concurs with the recommendation. The Board, Department, and the State Information Technology Services Division (SITSD) understand the importance of ensuring appropriate security of the system in coordination with the vendor. The Department agrees that MPDR data security can be strengthened by implementing a HIPAA compliant security plan which documents current procedures and implements additional procedures as necessary. The Department engaged expertise to complete a risk assessment of the MPDR system. This assessment follows the NIST 800-53 and 800-60 guidelines and standards utilizing the risk management

framework. This includes completion of the System Security Plan (SSP) which includes a governance structure, a Plan of Action and Milestones, and an assessment of the access control families. The Department will complete the plan by June 2019. DLI will continue to apply the risk management lifecycle processes on an annual basis.

***Recommendation #4***

**We recommend the Department of Labor and Industry coordinate with the Board of Pharmacy to:**

- A. Establish a process to enforce review of Montana Prescription Drug Registry delegate users.**
- B. Develop and implement procedures to review administrative and vendor user activity.**

**Response:** The Department concurs with the recommendation. As LAD notes and as discussed in the response to Recommendation #8, the Department anticipates moving to a new system platform for the MPDR. Among other improvements, review of MPDR delegate users will be included in the system requirements for the new platform. Stronger enforcement of delegate relationship review and renewal will be required at certain timelines of the prescriber or pharmacist who delegated search authority. This change will also enhance review of administrative and vendor users. In addition, the final SSP will require review of administrative and vendor user activity.

***Recommendation #5***

**We recommend the Department of Labor and Industry work with the Board of Pharmacy to implement formal procedures to ensure validation and quality assurance of Montana Prescription Drug Registry data.**

**Response:** The Department concurs with the recommendation. The Department agrees that development and use of enhanced system functionality will improve the quality and integrity of MPDR data as reported to the MPDR system by pharmacies dispensing controlled substance prescriptions. As discussed in the response to Recommendation #8, the Department anticipates moving to a new system platform for the MPDR. The Department will include enhanced data validation and quality assurance functionality in the system requirements for the new platform. In order to determine what data validations will best support the purpose to protect public health, the Department will work with its customers who use the MPDR and with the Advisory Group discussed in Recommendation #9. The Department will follow best practices to determine what types of data validation will follow best practices to achieve quality assurance.

***Recommendation #6***

**We recommend the Board of Pharmacy follow administrative rule by requiring all data elements in pharmacy reporting be included in the Montana Prescription Drug Registry.**



**Response:** The Department concurs with the recommendation. The Department agrees that usefulness of the MPDR data can be improved through system functionality which ensures the prescription data reported by pharmacies includes all data elements required by administrative rule. As mentioned in Recommendation #8, the Department anticipates moving to a new system platform for the MPDR. The Department will include functionality which better ensures the collection of all currently required data elements in the system requirements for the new platform. The Board will also consider a rule change to require use of the updated version of the ASAP standard for pharmacy reporting at the July 19, 2019 meeting. A new platform will also enable new required data elements supported in the updated ASAP standard.

***Recommendation #7***

**We recommend the Department of Labor and Industry work with the Board of Pharmacy to protect patient safety and public health by developing and implementing data analysis tools and procedures to identify and address potential misuse and diversion of prescription drugs using Montana Prescription Drug Registry data.**

**Response:** The Department concurs with the recommendation. The Department believes the MPDR has been and continues to be a useful tool to protect public health. The Department agrees the usefulness of MPDR data can be improved through the development of system functionality which automates the analysis of MPDR data. The Department anticipates moving to a new system platform which will include functionality that identifies and reports activity meeting pre-determined criteria and thresholds in the system requirements for the new platform. Such reports will include unsolicited reporting to prescribers and pharmacists, de-identified data for research and analysis, and improved statistical analysis. The Department and the Board will also engage the Advisory Group on such efforts.

***Recommendation #8***

**We recommend the Department of Labor and Industry and the Board of Pharmacy:**

- A. Conduct a formal analysis to determine the resources needed to properly manage the Montana Prescription Drug Registry.**
- B. Complete this analysis before a request-for-proposal for a new prescription drug registry.**

**Response:** The Department concurs with the recommendation. The Department will analyze the operation/oversight of the MPDR and determine the additional resources needed. As LAD notes, the Department anticipates moving to a new system platform for the MPDR. Prior to determining requirements for a new platform, the Department will define what elements should be in place for successful management of the MPDR, to include staff expertise, leveraging of other Department/Statewide resources, and management/security governance structure. The Department notes that any analysis of resource needs must consider both staffing levels and the funding structure. Currently, the statutory funding structure of the MPDR rests on licensing fees



paid by health care providers. Any resource decisions regarding this program must take into consideration this structure. The Department does not support significantly increasing fees on providers. The Department will complete this review by August 2019.

**Recommendation #9**

**We recommend the Board of Pharmacy work with the Prescription Drug Advisory Group to:**

- A. Establish formal policies and procedures regarding business processes which include regular, ongoing meetings.**
- B. Expand advisory group membership to include other stakeholders important to prescription drug evaluations and discussions.**
- C. Establish clear definitions of misuse and diversion of prescription drugs and update definitions in administrative rules.**

**Response:** The Department concurs with the recommendation. The Department agrees input from the Prescription Drug Advisory Group is critical to management of the MPDR and will continue to seek their input. A specific agenda item to facilitate discussion of this recommendation has been placed on the agenda for the July 19, 2019 Board of Pharmacy full board meeting.

In closing, the Department of Labor and Industry expresses our appreciation to the Board of Pharmacy and department personnel for their cooperation and assistance during the audit process; and to the Legislative Audit personnel for their diligence in exploring a broad and complex topic. As a Department we continually strive to improve our systems and processes as information and technology evolve. The MPDR is just one of the tools used by the State of Montana to protect patient safety and public health; and to help reduce misuse and diversion of controlled substances. As the auditors noted, in conjunction with other tools and the MPDR becoming functional in 2012, overdose deaths in Montana have decreased from 2006 to 2016 as national trends sadly trend upwards. DLI looks forward to working with legislators, MPDR stakeholders and citizens to continue to improve and maximize the potential of this tool; which in the end benefits all Montanans.

Sincerely,

Galen Hollenbaugh  
Commissioner  
Department of Labor and Industry

CC: Todd Younkin, BSD Administrator